

DIAGNOSTIC ULTRASOUND PRO SCANNER

MANUAL BOOK

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CAUTION

In the United States, Federal law restricts this device to sale, distribution, and use by or on order of a licensed physician.

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1. General

1.1 Introduction

USG PRO SCANNER (hereinafter referred to as "this device") is a professional digital color ultrasonic diagnostic apparatus. It transmits ultrasound waves into the body tissues and displays the echo images of the tissues and blood flow accordingly.

This series includes the following models:

- Linear Probe Q5-7L
- Convex Probe Q5-3C
- Phased Array Probe Q5-2P

Principles of Operation

Medical ultrasound images are created by computer and digital memory from the transmission and reception of mechanical high-frequency waves applied through a probe. The mechanical ultrasound waves spread through the body, producing an echo where density changes occur. For example, in the case of human tissue, an echo is created where a signal passes from an adipose tissue (fat) region to a muscular tissue region. The echoes return to the probe where they are converted back into electrical signals. These echo signals are highly amplified and processed by several analog and digital circuits that use filters with many frequency and time response options to transform the high-frequency electrical signals into a series of digital image signals which are stored in memory. Once in memory, the image can be displayed in real-time on the image monitor. A probe is an accurate, solid-state device, providing multiple image formats. The digital design and use of solid-state components provide highly stable and consistent imaging performance with minimal required maintenance.

1.2 Contact Information

This device is developed and manufactured by PT. SINKO PRIMA ALLOY. Customer service representatives are available to answer questions and to provide maintenance and service. Please contact PT. SINKO PRIMA ALLOY representative for assistance.

Telephone : (62) 31 7482816, 7482835, 7492882

Fax : (62) 31 7482865

Email : sinkoprime@gmail.com

Website : www.indo-elitech.com

Address : Tambak Osowilangon Permai Blok E8, Jl. Osowilangon No.61
Surabaya 60191 – Indonesia

1.3 About This Document

- Before attempting to use this device, read and fully understand all contents in the document to properly operate this device, paying particular attention to all: Warnings, Cautions, Notes, and Notices. Due to space limitations, this manual does not make perfect, any problem please contact PT. SINKO PRIMA ALLOY technical staff.
- In order to use the device correctly, keep this manual with the device at all time.
- This manual accompanies the USG PRO SCANNER only.
- The most extensive configuration is described within this manual, including the maximum number of the options and the accessories. Not every function, option or accessory described may have been purchased or licensed on your device.
- This manual forms part of the accompanying documentation for this product. The remaining documents in the set are listed: Advanced Technical Manual, Service Manual.

1.4 Product description

This device is a professional, premium performance real-time scanning system. The various probes make many applications possible.

This device provides the following diagnostic possibilities:

- 2D mode, M mode
- CF and PDI mode
- Spectral Doppler: pulsed wave (PW)

Intended use:

This device is indicated for Abdominal; Fetal/Obstetrics; Gynecology; Urology (including prostate); Cardiac (adult and child); Peripheral Vascular; Small Organs/Parts (thyroid, breast, testicle, musculo-skeletal Conventional and Superficial); Pediatrics (including neonatal cephalic); Interventional (nerve block and vascular access); Intraoperative (abdominal, brain) and Adult Cephalic Diagnostic Ultrasound applications. The device output is a valuable assisting medical tool for the diagnosis of disease, abnormality or follow-up.

This device is intended to use by, or by the order of, and under the supervision of a licensed physician qualified to direct the use of the device.

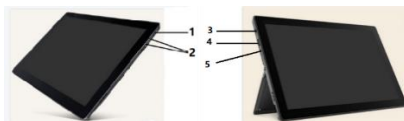
Patient population

Age : all ages (including embryos and fetuses)
Sex : male and female
Weight : all weight categories

Contraindication

The products are not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.

1.5 Mechanical System Monitor



1. Standby key
2. Audio Volume keys
3. Probe slot
4. USB port
5. Power port

Probe



1. Left Key
2. Middle Key
3. Right Key

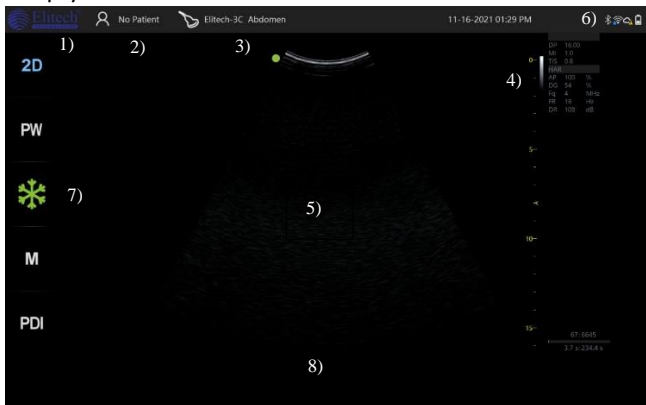
These 3 keys can be configured to different functions: freeze, store and so on. Please refer "Extended key" in "Sys Setting".

Touch panel

The touch panel is highly sensitive and consists of a flat monitor. It is easy to operate even under dim light conditions and allows for comfortable access to the control menu.

Notes: This touch panel can be blocked by a strong magnetic field. Avoid magnetic field interference. The touch panel may be impacted by any foreign body lying on it. To guarantee maximum performance, it is recommended to clean the touch panel regularly.

1.6 Display Annotation



- 1) Hospital name. It can be edited in “SysSetting”
- 2) Patient name and ID. Click here to display patient information: Name, ID, birthday/age, and OB info. If store some images, display their snapshots here too.
- 3) The current probe and app.
- 4) Display the values of MI and TI here, and other parameters value in different modes.
- 5) Image area: it is the field where the image is displayed.
- 6) Display the status of Bluetooth, WIFI, battery here. Click this area to display more detail information.
- 7) Mode and function buttons: click these buttons to enter the related mode or function.
- 8) Display available parameters here, click one parameter to display its value and buttons for adjustment.

Parameter Term Explanation

All parameters in the parameter field are abbreviated and stand for the following meanings.

| | |
|----|------------------|
| AP | : Acoustic Power |
| DG | : Digital Gain |
| Fq | : Frequency |
| WF | : Wall Filter |
| DR | : Dynamic Range |
| FR | : Frame Rate |
| SD | : Sample Depth |

1.7 Online Manual

In the system setting menu of the touch panel, there is a "User Manual" button. By selecting this key, the operator manual will be displayed for operator to refer to.

2. Safety

2.1 Introduction

This device is designed for the safety of the patient and operator. Before operating the device, read this chapter thoroughly with care please. The manufacturer guarantees the safety and reliability of the device only if all cautions and warnings are followed. Strictly observe all Warnings, Cautions, Notes and Safety markings within this document and on the machine.

Icon description:

Several levels of safety precautions may be found in this manual. Different levels of concern are identified by one of the following icons with signal words.



WARNING

Indicates a hazard which, if not avoided, could result in death or serious injury.



CAUTION

Indicates a hazard which, if not avoided, could result in moderate or minor injury and property damage.

2.2 Owner Responsibility

Notice against operator modification:



WARNING

Never modify this device, including the system components, the software, the cables and any other device components or accessories. A safety hazard may occur resulting from unauthorized modification. Do not attempt to disassemble the device if you are not trained and authorized by the manufacturer.

The operator must familiarize themselves with these safety measures and avoid situations that can result in injury or damage.

Do not dispose of this system (or any parts of it) with industrial or domestic waste. The system may contain materials such as lead, tungsten, or oil, or other hazardous substances that can cause serious environmental pollution. The system also contains privacy-sensitive information, which should be properly removed (scrubbed). Please contact PT. SINKO PRIMA ALLOY before disposing of this system.

Do not use this device during service or maintenance.

2.3 Regulatory Notice

This device has been tested to meet all applicable requirements.

According to 93/42 EEC (Medical Devices Directive) amended by 2007/47/EC, it is a class II a medical device.

Conformity to Standards:

The following standards have been used and the product is therefore certified in compliance with: IEC 60601-1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2: 2014 Electromagnetic compatibility - Requirements and tests

IEC 60601-1-6:2010 Usability

IEC 60601-2-37:2007+A1:2015 Medical electrical equipment - Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.

IEC 61157:2007/AMD1:2013 Declaration of acoustic output parameters

ISO 10993-1:2018 Biological evaluation of medical devices

IEC 62304:2015 Medical device software –Software life cycle processes













IEC 62366:2007+A1:2014 Medical devices - Application of usability engineering to medical devices

Council Directive 93/42/EEC amended by 2007/47/EC on Medical Device

WEEE according to 2012/19/EU

RoHS according to 2011/65/EU

2.4 Label Icon Description

| Label | Description | Location |
|---|---|-------------------------------|
|  | This is the indicator for company address. | Rear of main unit |
|  | This is the serial number indicator. | Rear of main unit |
|  | This indicates manufacture time. | Rear of main unit |
|  | MUST read the manual book. | Rear of main unit |
|  | Must read the Standard Operational Procedure | Rear of main unit |
|  | This is type BF equipment, in which protection against the electric shock does not rely on the basic insulation only. The operator shall provide additional safety precautions such as double insulation or reinforced insulation for protective earthing or reliance upon installation | Rear of main unit |
|  | This symbol indicates that the waste of electrical and the electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment. | User manual and power adapter |
|  | Standby button Warning: System shutdown using the "Standby" button does not disconnect the ultrasound unit from the main voltage. To disconnect the ultrasound unit from the main voltage after the system shutdown, plug out the power cable from the main outlet. | Computer |
|  | This indicates the approximate weight of the system in kilograms | User Manual |
|  | Direct current | Rear of main unit |
|  | Class II Equipment | Power adapter |
|  | Indoor use only | Power adapter |

2.5 Safety and Warning Notices

2.5.1 Acoustic Output

Definition of the acoustic output parameters:

Thermal Index: TI is an estimate of the temperature increase of the soft tissue or bone. There are three thermal index categories:

- **TIS:** soft tissue thermal index, the main TI category. Used for the applications that does not image (or visualize) bones.
- **TIB:** bone thermal index (bone located in a focal region). Used for the fetal application.
- **TIC:** cranial bone thermal index (bone located close to the surface). Used for the transcranial application.

Mechanical Index: MI is the estimated likelihood of tissue damage due to the cavitation.

Safety statement:



CAUTION

Although no harmful biological effects have been demonstrated for ultrasound frequencies, intensities and exposure times, we recommend the operator to use the lowest acoustic output settings producing acceptable diagnostic information.

Caution: Ultrasound can produce harmful effects in tissue and potentially result in patient injury. Always minimize exposure time and keep ultrasound levels low when there is no medical benefit. Use the principle of ALARA (As Low As Reasonably Achievable), increasing output only when needed to obtain diagnostic image quality. Observe the acoustic output display and be familiar with all controls affecting the output level. See the Bioeffects section of the Acoustic Output chapter in the Advanced Reference Manual for more information.

Caution: The operator of the device must sufficiently understand the acoustic output and be able to obtain the related thermal index values. The probe with self-heating in the air cannot be used in transvaginal scanning. Always minimize exposure time to the irradiation and keep ultrasound acoustic output level low for embryos or fetuses.

System controls affecting acoustic output:

The TI and MI show the highest possible acoustic intensity for a given mode, obtainable only when the combination of control settings that results in maximum output is selected. Most settings result in a much lower output.

There are several notes as follows:

- The duration of an ultrasound examination is as important as the acoustic output, since the patient exposure to output is directly relevant to the ultrasound scanning time.
- The better image quality can accelerate the clinical result, reducing the overall duration of an examination. Therefore, any image quality improvement can help to reduce patient exposure.

Probe selection:

As long as the appropriate application is available, any probe of this device can be used and meet the limitation of the acoustic output requirement.

Application selection:

Selecting the probe and application will provide the acoustic output within the limitation of the acoustic output requirement.

Changing imaging modes:

Acoustic output depends on the imaging mode selected. The choice of mode will greatly affect the energy absorbed by the tissue. After a combined mode is completed, such as 2D and CF mode, the total acoustic output comprises contributions from each individual mode.

Concerning surrounding fetal exposure:

Always be aware of the acoustic output level by observing the acoustic output display. The operator is recommended to become familiar with this device's controls affecting the acoustic output.

OB examination:



CAUTION

Prior to an ultrasound examination, the patient should be informed of the clinical applications which include specific benefits, potential risks and alternatives. In addition, if the patient

requires information about the exposure time and intensity, they should be provided. An ultrasound examination should not be performed to satisfy the family's desire to know the fetal sex: according to several countries' laws, which include China, using an ultrasound examination to detecting the fetal sex (gender) is prohibited.

2.5.2 Patient Safety



WARNING

The concerns listed in this section can seriously affect the safety of the patient undergoing a diagnostic ultrasound examination.

Patient Identification:

Always include proper identification with all patient data and verify the accuracy of the patient's name and/or the identity number after entering the data. Ensure all recorded data has the correct patient ID. Identification errors can result in an incorrect diagnosis.

Diagnostic Information:

The images and calculations provided by this device are intended for use by the competent the operator, as a diagnostic tool. They are explicitly not to be regarded as the sole basis for the clinical diagnosis. The operator is encouraged to study the literature and reach their own professional conclusions regarding the clinical utility of this device.



CAUTION

Special care is required to ensure the maximum privacy of the patient information.

2.5.3 Probe Safety

Mechanical hazards:



CAUTION

Damaged probes or the improper use of probes may result in injury or increased the risk of infection. The operator needs to frequently inspect the probe for damage, in particular looking for sharp or rough surface damage.



WARNING

If any defects or damages are found on the probe or its cable, DO NOT use the ultrasound diagnostic system. Contact your service representative.

Inspect probes frequently for cracks or openings in the housing and holes in and around acoustic lens or other damage.

2.5.4 Personnel and equipment safety

Explosion hazard:



WARNING

Never operate this device in the presence of flammable or explosive liquids, vapors or gases. The operator should be aware of the points to prevent such explosion hazards as follows:

- If flammable substances are detected in the environment, do not plug in or turn on this device. In addition, do not unplug or turn the device off if it has been turned on before.
- If flammable substances are detected, evacuate and ventilate the area before turning off this device.

Electrical Hazard:



WARNING

- Internal circuits of this device use high voltages, capable of causing serious injury or death by the electric shock.
- The OPERATOR MUST NOT touch accessible LIVE parts of USB, Type C ports and the PATIENT simultaneously.
- USB and type C ports: ONLY connect the PARTS or DEVICES which DO NOT have the external electrical hazard risk.
- USB port max. output 5V, 0.5A.
- Type C port max. output 5V, 2A.
- Please use USB devices which meet IEC 60950.

Any configurations by such connection must comply with the requirements of the IEC60601-1. It is the responsibility of the person who connects the parts or devices and configures a medical system to verify that this device complies with the requirements of the IEC60601-1. If you have any questions, contact your service representative for information.



WARNING

The probe and software, along with a representative notebook computer, have been verified as compliant with IEC 60601-1. The probe meets Type BF isolated applied part requirements. When

the probe and software are used in conjunction with a device compliant with IEC 60950-1, the system meets requirements of IEC 60601-1 for internally powered equipment.



Risk of electric shock.

The AC adapter must be disconnected before scan the patient when the AC adapter used is not model LXCP52(II)-020.



Device which comply with IEC 60950-1 have not been evaluated for compliance with the IEC 60601-1 temperature limits for patient contact. Therefore, only the operator is allowed to handle the device.

To avoid injury:



- Do not remove this device's protective covers. No operator-serviceable parts are inside. If servicing is required, contact a qualified technician.
- Device in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.
- Do not place liquids on or above this device. Conductive fluids seeping into the active circuit components may cause a short circuit, which can result in an electrical fire.
- An electrical hazard may exist if any light, monitor or visual indicator remains on after this device is turned off.



When using additional peripheral equipment that is to be interconnected by functional connection, the combination is considered to be a medical electrical system. If you have questions, contact your PT. SINKO PRIMA ALLOY representative.



If the system has been in an environment above 35°C (95°F), allow them to cool to operating temperature before turning on the system or connecting the transducers. Do not allow the transducer to contact the patient if the temperature of the transducer is higher than 43°C (109°F). Allow 30 minutes for the transducer to cool. If the transducers were only briefly exposed to temperatures above 35°C (95°F), then the time required for the devices to return to operating temperature could be less than 30 minutes.



CAUTION

Do not use this device if a safety problem is known to exist. This device needs to be verified by qualified service personnel before returning to use.

Pacemaker hazard:



WARNING

The possibility of this device interfering with pacemakers is minimal. However, as this device generates high frequency electrical signals, the operator should be aware of the potential hazard.

Monitor:



WARNING

To avoid injuries or system damage, NEVER place any object or liquid on the monitor.

DO NOT place any object on the ventilation slots. Blocking the ventilation slots obstructs proper airflow and may result in fire, electric shock, or equipment damage.

DO NOT scratch or press on the panel with any sharp objects, such as a pencil or pen, as this may result in damage to the monitor.

2.5.5 Electrical Safety

External connection of other peripheral devices:



CAUTION

Any unapproved external devices, such as laser cameras, printers and external monitors, usually exceed the medical standard allowable current leakage. If they are plugged into separate AC outlets and then connected to this device, it represents a violation of patient safety standards. Suitable electrical isolation of such external AC outlets may be required to meet the electrical leakage limit requirement.

Electromagnetic Compatibility (EMC):

This device can produce and use the radiation RF energy.

All types of electronic equipment may characteristically cause the electromagnetic interference with other equipment, either transmitted through air or connecting cables. The term EMC indicates the capability of this device to curb the electromagnetic influence from other equipment and at the same time not affect other equipment with the similar electromagnetic radiation from itself.

This product is designed to fully comply with the EN60601-1-2 (IEC60601-1-2), Class A, in medical electric equipment EMC regulations.

Proper installation following the service manual is required in order to achieve the full EMC performance of the product.

In the event of issues relevant to EMC, (turning on/off this device is able to evaluate whether an EMC-relevant problem has occurred), the operator (or qualified service personnel) should try the measures (one or more) to address and solve the problem as follows:

- Determine the identity of the affected equipment and replace the affected equipment (one or more).
- Relocate this device or the affected equipment to increase the distance in between.
- Use a different power supply source from the affected equipment for this device's power supply.
- Call your service personnel for more advice please.

General Information

1. Locate this device as far away as possible from other electronic equipment. This product is suitable for hospitals or clinics except for near active HF surgical equipment and the RF shielded room of and medical system for magnetic resonance imaging, where the intensity of EM disturbances is high.

2. Be sure to use only the cables provided by or designated by PT. SINKO PRIMA ALLOY company. Connect these cables following the installation procedures (i.e. wire power cables separately from signal cables).
3. Avoid using equipment not designated for this device. Failure to comply with this instruction may result in poor EMC performance of the product.
4. Notice against Operator Modification:
Never modify this product. Unilateral operator modification may cause the degradation in EMC performance and may lead to the serious hazards for the patient and the operator. Modification of the product includes:
 - a. Changes in the cables (length, material, wiring etc.)
 - b. Changes in the system insulation/layout.
 - c. Changes in the system configuration/components.
 - d. Changes in the securing system parts (cover open/close).
5. Operate this device with all covers closed. If a cover is opened for any reason, ensure that is shut before starting/resuming operation.
6. The representative notebook computer is integrated with a wireless module, which utilize three frequency band to interchange data with other RF device. We have get all that band information below.
5725-5850 MHz (WIFI) Bandwidth: < 80MHz TX power: <33dBm Modulation: OFDM
5150-5350 MHz (WIFI) Bandwidth: < 40MHz TX power: <23dBm Modulation: OFDM
2400-2483.5 MHz (BLUETOOTH WIFI) Bandwidth: < 20MHz TX power: <20dBm
Modulation: DSSS GFSK
7. The probe used with the system may affect its emissions. The probe listed in probes on section 10.2, when used with the system, the EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as or re-orienting the equipment.
8. Essential performance
The ability to display physiological images as input for diagnosis by trained physician. The ability to display physiological traces as aid for diagnosis by trained physician.
The ability to display quantified data including distance, angle, square, etc., as input for diagnosis by trained physician.
The display of ultrasound indices as aid for safe use of the unit.
NOTE: Operating this device with any cover open may affect EMC performance.
9. Approved accessories for Electromagnetic compliance

Accessories used with system may affect the emissions result. The probes listed on section 10.2, when used with the system, have been tested to comply with Group 1, Class A emissions as required by international standard CISPR 11. Use the listed accessories only. When connecting other accessories to the system, such as foot switch, printer or computer, it is the user's responsibility to ensure the electromagnetic compatibility of the system. Use only CISPR 11 or CISPR 32, Class A-compliant devices, unless otherwise noted.



WARNING

Do not use the following devices near this Ultrasonic system: Devices which transmit radio waves such as cellular phones, radio transceivers, mobile radio transmitter, radio-controlled toy, etc. Use of these devices can cause this Ultrasonic system to perform outside the certified specifications. Keep these devices powered off when kept near this device. Medical staff in charge of this device is required to instruct technicians, patients and other people who may be around this device to fully comply with the above regulations.



WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



WARNING

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

| Information of all the cables | | | | | |
|--------------------------------------|------------|----------|----------------|----------------|--|
| Port No. | Name | Type | Cable Max >3 m | Cable Shielded | Comments (SIP/ SOP lines must include description of use |
| 0 | Enclosure | N/E | - | - | |
| 1 | Mains | AC | >3 m | Unshielded | AC mains port |
| 2 | Probe | PC | <3 m | Unshielded | Ultrasonic diagnostic |
| 3 | USB (1 Pc) | SIP/ SOP | <3 m | Shielded | USB port for data transmission, |

| | | | | | |
|---|--|--|--|--|----------------------------|
| | | | | | connection with USB device |
| Supplementary information: Note: AC = AC Power Port; DC = DC Power Port; N/E = Non-electrical; Batt = Battery; SIP/ SOP = Signal Input/ Output Port; PC – Patient-Coupled Cable; TP = Telecommunication Ports | | | | | |



WARNING

Even though this product complies with EMC requirements for a Group 1, Class A Medical device as stated in IEC 60601-1-2, this equipment still can be electromagnetic influenced by other electronic equipment.

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Electromagnetic emission:

| Guidance and manufacturer's declaration – electromagnetic emissions | |
|--|---|
| This device is suitable for use in the specified electromagnetic environment and it has meet the following standard's emission requirements. | |
| Phenomenon | Professional healthcare facility environment |
| Conducted and radiated RF emissions | CISPR 11, Group 1, Class A |
| Harmonic distortion | IEC 60601-3-2, Class A |
| Voltage fluctuations and flicker | IEC 61000-3-3 |



WARNING

Radiated, conducted electromagnetic signals or electrical fast transient pulse group can cause distortion, degradation, or artifacts in the ultrasound image which may impair the ultrasound system's essential performance.

Electromagnetic immunity:

| Guidance and manufacturer's declaration – electromagnetic immunity | | |
|--|--|--|
| This device is suitable for use in the specified electromagnetic environment and it has meet the following immunity test levels. Higher immunity levels may cause the device's essential performance lost or degraded. | | |
| Phenomenon | Basic EMC standard or test method | Professional healthcare facility environment |
| Electrostatic discharge | IEC 61000-4-2 | +/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 k V air |
| Radiated RF EM fields | IEC 61000-4-3 | 3V/m 80MHz-2.7GHz 80%AM at 1 kHz |
| Proximity fields from RF wireless communications equipment | IEC 61000-4-3 | See the RF wireless communication equipment table in "Recommended minimum separation distances" |
| Rated power frequency | IEC 61000-4-8 | 30A/m, 50 Hz or 60 Hz |
| Electric fast transients | IEC 61000-4-4 | ±2kV,100kHz repetition frequency For input a.c. power port d.c. power lines or signal input/output lines whose length exceeding 3m |
| Surges | IEC 61000-4-5 | Line to line: ±0.5kV, ±1kV Line to earth: ±0.5kV, ±1kV, ±2kV For 1. input a.c. power port; All d.c. power ports connected permanently to cables > 3m Output signal output lines connected directly to outdoor cables |
| Conducted disturbances induced by RF fields. | IEC 61000-4-6 | 3 V in 0.15 MHz - 80 MHz 6 V in ISM and/or amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz or 2 Hz (test performed at 2 Hz is worst case as identified for risk management) (system compliant to 10 V immunity test level) For input a.c. power port; all d.c. power ports connected permanently to cables > 3 m. All patient-coupled cables SIP/SOP whose maximum cable length ≥ 3m |

| | | |
|---|----------------|---|
| Voltage dips | IEC 61000-4-11 | 0% UT: 0.5 cycle at 0o, 45o, 90o, 135o, 180o, 225o, 270o and 315o |
| | | 0% UT: 1 cycle and 70% UT: 25/30 cycle sine phase at 0o. |
| Voltage interruptions | IEC 61000-4-11 | 0% UT: 250/300 cycle |
| UT: rated voltage(s); E.g. 25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60 Hz | | |



WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Recommended separation distances:

| Recommended separation distances between portable and mobile RF communications equipment and this device | | | | | | |
|---|------------|---------------------|--|-------------------|--------------|---------------------------|
| Nowadays, many RF wireless equipment have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or system's basic safety and essential performance may be affected. This product has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2: 2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and this ultrasound diagnostic system as recommended below. | | | | | | |
| Test Frequency (MHz) | Band (MHz) | Service | Modulation | Maximum Power (W) | Distance (m) | Immunity Test Level (V/m) |
| 385 | 380-390 | TETRA 400 | Pulse modulation 18 Hz | 1.8 | 0.3 | 27 |
| 450 | 430-470 | GMRS 460 RFS 460 | FM ± 5 kHz Deviation 1 kHz sine | 2 | 0.3 | 28 |
| 710 | | | | 0.2 | 0.3 | 9 |

| | | | | | | |
|------|-----------|---|-------------------------|---|-----|----|
| 745 | 704-787 | LTE Band 13, 17 | Pulse modulation 217 Hz | | | |
| 780 | | | | | | |
| 810 | 800-960 | GSM 800/900; TETRA 800; iDEN 820; CDMA 850; LTE Band 5 | Pulse modulation 18 Hz | 2 | 0.3 | 28 |
| 870 | | | | | | |
| 930 | | | | | | |
| 1720 | 1700-1990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| 1845 | | | | | | |
| 1970 | | | | | | |
| 2450 | 2400-2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE B | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| 5240 | 5100-5800 | WLAN 802.11 a/n | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| 5500 | | | | | | |
| 5785 | | | | | | |

3. Start the system

3.1 General

The first installation must only be performed by authorized personnel. The system has a default setting which is applicable for most cases. Experienced operator can change the default setting and store it as an operator-defined setting. This device must be in the proper environment. This applies to in the operation, storage and transport. Requirements of the environments are listed as shown below:

| Requirement | Temperature | Humidity | Air pressure |
|--------------------|-------------|----------|----------------|
| Transport/shipping | -5 - 50°C | 10 - 80% | 700 – 1060 hPa |
| Storage | -5 - 50°C | 10 - 80% | 700 – 1060 hPa |
| Operation | 10 - 35°C | 30 - 75% | 700 – 1060 hPa |

3.2 Safety warnings



CAUTION

When this device is moved from a cold environment such as the stock room into a warm room, it is necessary to wait several hours for the machine to dehumidify before starting the machine due to the temperature change of the environment.

3.3 Power on/ Boot up

1. Connect the power cable to this device. Plug the power cable into a hospital grade power socket with the proper rated voltage.
2. Or use the battery.
3. Push the "Standby" button on the control panel. After the system is switched on and booted up for one minute, the default applied 2D image for the selected transducer is displayed. All peripherals which are connected to the outlets of this device can be switched on only after the system is switched on.



WARNING

The MAINS plug or an appliance coupler is used as the disconnect device, the disconnect device shall remain readily operable.

3.4 Power off/ Shutdown



CAUTION

To avoid loss of the current patient data as well as all the measurement data, it is necessary to save the data to one patient before switching off this device. If not saved, this device will display a warning after re-booting.

Push the "Standby" switch to shut down the system.



WARNING

System shutdown using the "Standby" button does not disconnect the ultrasound unit from the main voltage. To disconnect the ultrasound unit from the main voltage after the system shutdown, plug out the power cable from the main outlet.

3.5 Probe and Application Selection

3.5.1 Plug Probe Connector into This Device


The probe plug process is as follows:

Plug this device into probe slot or USB 3.0 port of Pad monitor.

3.5.2 Probe and Application Selection

Touch probe icon to open "Probe&App", applications can be switched here.

Operator defined setting:

Select configuration icon  to enter "Probe&App" page. In this page, the operator can add one user-defined application, or delete one user-defined application. And rename the user-defined application, set one application as default, and reset all changes.


Select "Edit", applications can be hidden by un-selecting them.

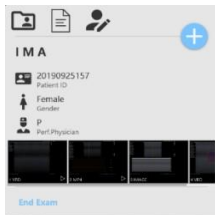
If the current application is one user-defined application, adjust some parameters, enter "Probe&App", select "Save" or "Save&Exit", the changes can be saved to the current application.

3.5.3 Probe keys configurations

There are 3 keys on each probe, they can be configured as different functions. Please read chapter "Sys Setting\Extended key" for reference.

3.6 Image Storage


Touch "Store" icon  to save VRD, DICOM or AVI image to the system harddisk. In system setting, the destination and format of storing image can be configured. All saved images will be displayed on the clipboard, please touch patient icon to replay them.



Save the image during scanning, it will be cine. Save the image after freeze the system, it will be one frame.

Please use the specified USB device.

3.7 Freeze image

Touch "Freeze" icon  the system to switch from the scan mode to the frozen mode. When the icon is orange, it is in frozen mode which means the image is static. When the icon is green, it is real scan mode in which the scan image is in real time.


Select "New Patient", "Archive", "Probe & App", "SysSetting", "Measure" or "Body Pattern", the system will switch to frozen mode.

3.8 Patient data

Normally the operator needs to input a new patient's information before scanning the new patient. Alternatively, pull up an old patient's data from the archive for a new examination of the old patient. Read chapter 4 for reference.

3.9 Image Annotation

3.9.1 Character Annotation

Slide the touch panel from left edge to right, "Comments", "BodyPattern" and "Measure" buttons are displayed. Touch "Comments" button  to enter "Comments" page, touch "Comments" button, exit comments.

At the bottom there are some frequent terms, they can be added on the image by dragging or touching them. Those words will be different based on different applications and probes. Select and hold a certain section of the image area for adding annotations. By selecting and holding the previous comment, it can be edited, with edit field turned green. After the other field is selected, the previous annotation will become a confirmed annotation.

After the "Delete" is selected, this button will be highlighted and there will be a delete sign appearing beside each comment, the comment can be deleted by selecting the delete sign. After the "Delete" is selected again, this key will return to normal and the delete sign for each comment will disappear.

3.9.2 Arrow Indicator

Drag arrow indicators on the comment screen to move them to the image area to indicate the nidus. Arrow can be rotated after it is selected.

3.9.3 Body Pattern



Touch "BodyPattern" button, all body patterns are displayed at the bottom. After one of those patterns is selected, the body pattern box will turn green and the body pattern will appear on the bottom-right side of the image screen for reference. The probe indicator's orientation and position can be changed. Touch the body pattern on the image to confirm the selection. Touch "BodyPattern" button again, exit "BodyPattern".

Note that after returning to the basic UI, the body pattern and probe indicator cannot be changed. By selecting "Body Pattern" again, the probe indicator's direction and position can be changed.

Select "Import" to import body patterns from a USB memory stick. After the "Import" key is selected, the operator can follow the procedure to import body patterns. In this case, the operator has to copy a body pattern from his own PC in JPEG format.

In system setting, the size of body pattern can be adjusted.

3.10 Cine Mode

While scanning a certain number of frames, after "Freeze" button is touched, touch the image area, there is one triangle blue button. Touch the button, the sequence will be replayed continuously. By sliding on the touch panel horizontally the sequence can be reviewed frame by frame.

This length of cine loop depends on the number of the scan lines, the scan depth and other parameters.

Note:

1. Start Frame, End Frame: control which frame to start from and which to end in order to display continuously as a loop.
2. Speed: controls cine speed as 400%, 200%, 100%, 60%, 50%, 40%, 20%.

3.11 Zoom function

Zoom the image with two fingers. Two fingers touch and hold on the image, then move the fingers to increase the distance between them, the image will be zoomed in. The opposite operation will zoom out the image.

3.12 Multiple display formats

Select buttons on the touch panel ("Dual", "Quad", and "A", "B", "C" and "D").

After "Dual" on the touch panel is selected, the system will have dual image display. "A" position image will be real time and "A" button will be highlighted by default. "B" position image will be last frame static image at the same mode.

Select "B" button to active the "B" position image. The "B" button will be highlighted.

Selecting "single" display format button will go back to the normal one image display.

After "Quarter" on the touch panel is selected, the system will have quarter image display. "A" position image will be real time and "A" button will be highlighted by default, and the "A" button is highlighted. The "B", "C" and "D" are the last frame static image.

Select the "B", "C" or "D" button to activate "B", "C" or "D" position image. Only one image can be activated at one time.

Selecting "single" display format button will go back to the normal one image display.

3.13 2D Image size change

In 2D mode, slide up from the bottom. There is a parameter "Image Angle". This parameter is used to adjust the image size.

4. Prepare for an Examination and Patient Data Archive

Before starting an examination, it is recommended to enter a new patient's information before begin to scan. The patient information can also be entered while scanning, but the operator needs to determine whether the corresponding image belongs to the patient or not before storing. The operator can pull out the patient's information from the archive and start a new examination. The patient information is the same as before.

For new patient information, the recommendations are as follows:


1. Patient ID.
2. Patient name.
3. Date of Birth/age, gender.

This is stored together with the patient's images and will be transferred with the images of the corresponding patient to the archive.

The information and application data below may differ in different examinations and we recommend that it should also be entered.

1. Physician, operator.
2. Basic data in relevant application category.

4.1 Beginning a New Patient

Touch patient info area, touch  button in pop-up window, enter "New Patient" page, there will be an auto ID in "Patient ID", the operator can use this ID or input her/his own one. If set "prefix" in system setting, the prefix will be added. Select "Exit" to go back to the main menu without saving the information. If the operator inputs some information on this page, and select "Save&Exit" the system will create a "new patient" record and store this information to start scanning.

Note:

1. BSA is body's surface area, and will be automatically calculated when the data above (weight and height) is filled in.

2. The empty box is the data input field. After the relevant place is selected, they can be selected to input number or characters.
3. Either birth date or age needs to be filled in, the other one will be automatically calculated based on the time of the system. For this reason, it is very important that the system time be correct. There are three gender options: N/A, male or female.
4. If the inputted ID is the same with the existed one, the system will give one warning message: There're some patient records match the creating patient, do you want to view details?

If there is no patient ID or name, select "Save & Exit" on the touch panel and the system will display a message for three options to select from. The options are: "Exit without new patient", "New patient with auto ID" and "Go back to patient page". Select "New patient with auto ID" and the system will automatically give a number for new patient ID. Select "Exit without new patient" and the system will go back to real scan mode without patient ID. If "Go back to patient page" is selected, the system will go back to the new patient page.

4.1.1 General Data Section

Patient ID : ID number, max 30 characters.

Second ID : ID number, max 15 characters.

Family Name : patient's family name, max 20 characters.

Middle Name : patient's last name, max 20 characters.

First Name : patient's first name, max 20 characters.

Birth Day : patient's date of birth.

Age : patient's age (the age is calculated and displayed automatically after entering birth date).

Sex : N/A, female, male (pull down menu).

Perf.Physician: Name of the performing physician, max 30 characters. Ref. Physician: Name of the referring physician, max 30 characters. Operator: Name of the operator, max input is 30 characters.

4.1.2 Application data information section

General : This category has the basic patient information for many applications. In this section, enter height and weight, and then BSA (body surface area) will be calculated automatically.

OB : patient information for obstetrics.

GYN : patient information for gynecology.

UR : patient information for urology.

CARD : patient information for cardiac

The OB application patient information section contains the below items:

1. LMP: last menstrual period, enter the first day of the last menstrual period.
2. BBT: basal body temperature, enter the date of the most recently recorded basal body temperature before the last menstrual period. Data cannot be entered in this field if LMP data was entered before.
It is possible to enter data for either LMP or BBT. Then the EDD and GA will be calculated based on the LMP or BBT.
3. DOC: Date of conception.
4. IVF: Date of in vitro fertilization.
5. GA: Gestational age. Select the date of the last exam and the GA of the last exam, it will display the current GA. Or it will be calculated after entering LMP/BBT/DOC/IVF. Or input GA manually, then get EDD automatically.
6. EDD: Physician should either enter the estimated date of delivery, or this can be automatically calculated after entering the LMP or BBT. If "EDD" is entered, the "LMP" and "GA" can be calculated.
7. Gravida: enter the patient's history of pregnancies.
8. Para: enter the patient's history of live births.
9. AB: enter the patient's history of abortions.
10. Ectopic: enter the patient's history of ectopic pregnancies.
11. Fetus: select the number of fetus(es) (1 to 4).

GYN application patient information section contains the below items:

1. LMP: last menstrual period, enter the first day of the last menstrual period.
2. Gravida: enter the patient's history of pregnancies.
3. Para: enter the patient's history of live births.
4. AB: enter the patient's history of abortions.
5. Ectopic: enter the patient's history of ectopic pregnancies.

UR application patient information field contains the below items:

1. PSA: prostate specific antigen, enter the value of it.
2. PPSA Coefficient: enter the value of the predicted PSA coefficient.

CARD application patient information section contains the below items:

1. BP: enter the value of the BP manually.
2. HR: enter the value of HR manually.

If the operator does not want to enter all the data, the examination can be started by selecting "v".

Note: If there are some temporary measurement results or saved images without entering any patient's information and without storage, when touch "New Patient", an information dialog for

option will appear. If select "OK", the current images and the measurement results will be stored in the new patient's archive. If select "Cancel", the images and the measurement results will be stored to new patient automatically.

4.1.3 Indication Message

| ID | Scenario | Indication message |
|----|---|---|
| 1 | Touch "v" button with no patient's ID or name inputted in New Patient page. | The system generates the patient ID by default and enters the scan mode directly. |
| 2 | If inputted patient ID is the same as one existed patient ID in New Patient page. | There're some patient id or name match the creating patient, go and see details. |
| 3 | Touch "Archive" or "New Patient" if there is some unsaved data. | Do you want to attach the previous exam data to this new patient? |
| 4 | Select one or more patients, touch "Delete Patient" in Archive page. | Are you sure to delete the selected patient(s)? |
| 5 | Select one exam, touch "Delete Exam" in Archive page. | Are you sure to delete the selected exam(s)? |
| 6 | Export the same patients to the USB device. | There is exported data on the device and they will be totally deleted by following operation, do you want to continue? |
| 7 | There is no enough space on USB device when export patient data. | Export failed, no enough space left on USB or the device is removed. |
| 8 | Send one or more images through email in Archive, but email setting is not completed. | Email setting is not completed, please check it in "Sys Setting". |
| 9 | Change language. | You must restart system for changes to shut down for changes to take effect. Do you want to restart now continue? Please wait for 10 seconds, then start the machine again. |
| 10 | In Sys Setting/Features, the inputted license is not valid. | System detects that the input license is invalid or is not for this machine, please contact manufacturer for support. |

| | | |
|----|--|--|
| 11 | In SysSetting/ Features, the inputted license is valid. | Following options will be activated: Do you want to apply? If you choose OK, then license will be applied. |
| 12 | The system occurs unexpected exception. | Unexpected exception happens, the system will be shutdown. We are sorry about this. |
| 13 | Print one report while the printer is not connected. | Printer is offline. |
| 14 | Touch "Reset" in Probe&App page. | The presets of current probe will be restored to factory default value; do you want to continue? Which app of current probe do you want to restore to factory default value? Restore Current App. Restore All Factory Apps. Restore All apps. Cancel. |
| 15 | Save the changes in Probe&App page, or add one user-defined application. | Confirm to save? |


4.1.4 Worklist

After enable "Worklist" in system setting, there is a "Worklist" tab in "New Patient". And there is another tab "Local Data", display new patient content.

The system gets the patients from worklist server automatically when enter "Archive" if enable "Auto Load Worklist".

Choose the start and end date, then select "Search" to load all patients in this period. Choose one patient, select "Select Current" to start the exam. If capture some images, do some measurements or add some comments, the current patient will be saved to local data. If select "Today", only load the patients of the day. If select "Near week" or "Near Month", load the patients of the near week/near month. If input patient ID or name then select "Search", download the searched patient(s) from the worklist server.

4.2 Archive

Touch patient info area, touch " button in pop-up window, enter "Archive" page, back to main page, the system will go back to the scan mode.

4.2.1 Initial Archive Menu

Patient/Exam:

1. Select "New Exam" or "Tracking Exam", enter to corresponding exam page, refer to 4.2.2 for more details.

2. View: Select "View, only display one exam image.
3. View/Edit: "Select "View/Edit", all patient information can be edited if the selected exam is not ended and the patient is added in 24 hours. But only relevant application category's data can be edited if the patient is added 24 hours ago.
4. Multiple: Touch unfold icon, it can select multiple patients, touch the icon again, only can select one patient, touch "Delete" icon, selected patients can be deleted.
5. Search: In the initial entering, the latest patient's information will be displayed. In order to search certain files, input related text in the search input field.
6. Order: Touch "Patient ID", "Name", "Last Date", "Date of Birth", "Image Size", all patients in the list will be ordered as ascending or descending.
7. "Compare": During live scanning or select one image on the clipboard, enter "Archive", select one image of one patient, select "Compare", the system exit "Archive" and enter dual display format: on the right display live scanning image or the image selected on the clipboard, on the left display the image selected in "Archive".
8. Delete icon: Select one image of one patient, touch "Delete" icon, you can select whether to delete the image or not. Select one examination of one patient, touch "Delete" icon, you can select whether to delete the examination or not.
9. Report: Touch "Report", enter to Report page.
10. After "End Exam" in main menu is selected, the current patient's examination will cease the progress, at this moment there is no any patient is selected. the information of this exam can't be edited in Archive, and the button "Edit" in worksheet will be gone. New exam can be added in "Archive", or add a new patient.

Management:

1. Save patient data or snapshots & video to USB, DVD or Server. Please refer to chapter 4.2.3.
2. Send via Bluetooth: Image transmission via Bluetooth, please refer to Chapter 4.2.6.
3. Send via Email: Image transmission via Email, please refer to Chapter 4.2.7.

4.2.2 New Examination from Archive menu

After "New Exam" in "Archive" menu is selected:

1. Select "V" to add one new examination, the system will back to scan mode. Select "X", the system will go back to the "Archive" menu.
2. Any time after "Freeze" touched, the system will go to the scan mode in the original examination (not the new examination).

3. The previous information about the "Examination Physician", the "Ref Physician" and the "Operator" data will display in the relevant areas by default. The operator can also edit it by selecting this field.
4. "Accession number", "comments" and additional data of different category can be edited too.

4.2.3 Export Patient or Examination Data

Enter Archive, touch button "More...", there are different medias for storage.

- USB items: One is for patient data backup, another is for saving snapshot & video.
- DVD item: One is for patient data backup, another is for saving snapshot & video.
- Server items: One DICOM server, for uploading DICOM files. One vCloud server, for uploading Remote Image Data. Two file servers, for patient data backup and saving snapshot & video. And one FTP server, for saving snapshot & video.

Select one or more patients in the "Archive", if this device is connected to a USB, DVD device, or a server, the relevant button will be highlighted. Touching highlighted "Backup data" or "Save snapshot & video" button, enter the relevant page.

The position of these items can be moved. Touch the button and hold, then drag it to the destination position.

Backup data page:

- Button "VRD", "DICOM", "Image" and "Misc" are highlighted, the relevant images will be selected. All these 4 buttons are highlighted as default, so these 4 formats of images are selected and displayed.
- Button "Select All" is highlighted as default, all images are selected. Touch one image to unselect it.
- There are 3 kinds of media options for data backup: USB, DVD, File Server. If there are 2 USB disks, please select one of them.
- Touch "Backup" to back up the selected patients' data to the selected device, all selected images are saved.
- Patient data is saved in folder "VINNORepositoryV2". For example, one patient named "Test", ID is "123", then the saving path will be: USB disk\VINNORepositoryV2\[Test]-[123]- [XXXX]. "[Test]-[123]-[XXXX]" is one subfolder of "VINNORepositoryV2" named by patient name and ID.
- The backup data can be imported to PRO SCANNER machine.

Save Snapshot & Video

- Button "Select All" is highlighted as default, all images are selected. Touch one image to unselect it.

- There are 4 kinds of media options for saving snapshots & video: USB, DVD, FTP server and File Server. If there are 2 USB disks, please select one of them.
- After enable "Convert VRD to DICOM" or "Convert VRD to MP4", convert all selected VRD format files to DICOM/MP4, then save the images to USB/DVD/FTP/File server. These images are still VRD format in this machine.
- Convert Intervals: 1-30 seconds. After "Convert VRD to DICOM", set 10 seconds by default, convert the latest 10 seconds of one VRD image to MP4 image.
- Touch "Save" to store snapshots or video to the selected device.
- If the image format is AVI, save the video and the snapshot of the image to the media device.
- If the image format is VRD, DICOM or IMAGE, save the snapshot of the selected image to the media device.
- All these videos and snapshots saved in folder "PatientSnapshots". For example, one patient named "Test", ID is "123", saved these videos and snapshots on 2016-2-19, then the saving path will be: USB disk\ PatientSnapshots\2016-2-19\[Test]-[123]-[XXXX]. "2016-2-19" is one subfolder of "PatientSnapshots" named by the date, and "[Test]-[123]- [XXXX]" is one subfolder of "2016-2-19" named by patient name and ID.

If this device is connected to one DICOM server, DICOM images can be uploaded to the server:

- Display all DICOM images on the right.
- Touch "Convert VRD to DICOM" button, all VRD images will be displayed on the right too.
After start to upload images, all selected VRD images will be converted to DICOM images, then upload to DICOM server.
- Convert Intervals: DICOM Server:1-10 seconds. Set 6 seconds, convert the latest 6 seconds of one VRD image to DICOM image.
- Button "Select All" is highlighted as default, all images are selected. Touch one image to unselect it.
- Touch "Upload" to upload images to the server.

4.2.4 Import patient or examination data


Touch "Import" in the "Archive", enter to Import page. The operator can import the data and the information of the patients from the outside media. The operator can adjust that data once they are imported to the system.



Selecting the importing media (USB, DVD or Server) and can also use the search function to find the specific information about the corresponding patient in the importing media. By selecting one patient or more patient, or by touching "Select All" on the touch panel to select all files. Touching "Import" to starts the import process.

Go back to the "Archive" menu by touching "<".

Select one patient, slide the touch panel from right to left to obtain the examination file list. Then import one selected examination file from this menu. Slide the touch panel from left to right to obtain the patient list.

4.2.5 Report

Touch "Report"  in "Archive" or patient info area on main menu, enter Report page.

1. The measurement worksheet will be generated automatically without operator's operation.
2. The patient and the physician information will come from the database automatically. The information revised manually. After edit the patient data, select "Preview", the updated data will display in the report.
3. In "Image Zone", select one or more images, select "Preview", the selected images will appear in the report.
4. In "OB Graph", select "Store" to save the current graph, and this graph will appear in "Image Zone\OB Graph" in Report. Select "Preview", the graph will appear in the report.
5. In "Worksheet" select one probe/application, all results will be displayed. Select "Preview", the results will appear in the report.
If the current patient's fetus number is 2 or more, and do some measurements with every fetus, then enable "Fetus Compare" , all measurement results in every fetus will be listed in column.
6. In "Comments", the operator can input some comments here. Select "Preview", the comments will appear in the report.
7. In "Template", the operator can select "General", "OB" template, or different formats for multi images. Select "OB" template, in report there is some information of GA and EDD if do the related measurements.
8. Select "Store", this report can be saved.
9. Select "USB", save the report to one USB device.
10. Printer can be selected in the lower right corner. Enter configuration page to configure the settings of the selected printer.
11. Select  to enter configuration page, user can import user-defined template

4.2.6 Bluetooth

Enabled Bluetooth, select one patient in "Archive", touch "Send via Bluetooth" button to enter Bluetooth page.

After scanning, list all nearby Bluetooth devices. Select one device, and select one or more images, touch "Send" to send the images to the selected device. Before send the images, the system will pair with the remote device first.

4.2.7 Email

Before use Email, the operator needs to enable the network and set email settings in "SysSetting". Select one patient in "Archive", touch "Send via Email" button to enter Email page. Input one or more addressees, then select images, touch "Send" to send the images by email. After send successfully, the addressee(s) will be saved in the list.

4.2.8 View menu

After "View" in the "Archive" is selected, the system goes to the view function.

Note:

1. After entering the view mode, select the images, and then select "Single", or "Dual", or "Quad" to display the images in the different formats. Select the other images and the different view modes to be displayed. "Single" means that the image screen will display the first selected image. "Dual" means that the image screen will display the last two selected images as the dual image display format. "Quad" means that the image screen will display the last four selected images as the quarter image display format. Only VRD images can be displayed in dual or quad formats
 2. After small images are selected, the image box will be highlighted. If "Multi selection" is enabled, the first select in the relevant image means selection, the second select means un- selection.
 3. Select button "More" to enter "More" page, the operator can send images or video by touching "Send via Bluetooth" or "Send via Email". The operator can save images to DVD by touch "Export to DVD". Touch these buttons to enter relevant pages.
 4. By selecting "<", go back to the "Archive".
- 5. 2D Mode, M mode**
- 5.1 2D mode**

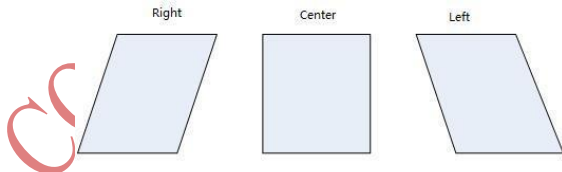
5.1.1 Main menu

In other mode, touch "2D" button to back to 2D mode. Slide up from the bottom of the screen to open 2D mode menu, displays all adjustable parameters, slide down the screen to hide menu. Touch one parameter, the sliding switch or the adjusting arrow button can be increased or decreased according to the different parameters selected. Slide right to display more parameters.

All available parameters are as follows:

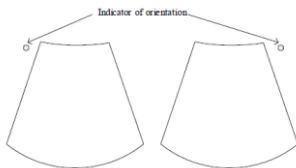
- **Image Quality:** Select different level "Resolution", "Normal", "Penetration" to adjust the image quality.
- **Frequency:** By regulating this parameter, the operator can strike a balance between resolution and penetration. High frequency generally means a better resolution at the cost of a worse penetration.
- **Focus Position:** It is to select the depth of current focus or focuses. The focus position is indicated on the right side.
- **Focus #:** This allows the operator to select the number of focuses. The number of focuses depends on the probe selected.
- **VFusion:** This function enhances the contrast resolution with better tissue differentiation and clear organ borders. When the level is 0, this function is switched off.
- **VSpeckle:** This function reduces the speckle noise in the ultrasound image.
Notes: This process smooths the image, so potentially some structures can be smeared out.
- **Dynamic Range:** This allows the operator to enhance the grayscale to make the image easier to display.
- **Line density:** This helps to keep a balance between the image resolution and the frame rate. A higher line density means a better resolution, but a slower frame rate.
- **VSharpen:** By this function, the edge of the image can be more easily observed with the naked eye. The higher the level of VSharpen, the better the edge of the image can be.
- **Image Angle:** This function can be used to change the scanning angle. A small angle can provide a faster frame rate, but the scanning area is smaller.
- **Persistence:** Frame averaging can eliminate the image speckle of the 2D images. Several frame averaging levels can be set in this menu.
- **Gray Filter:** Certain echo signals can be filtered by this function to avoid noise.
- **Smooth:** This smoothens out the image by reducing the number of pixels. Focus Width: Using this key change the focus zone width.
- **Acoustic Power:** This allows the operator to change the transmitted acoustic power.
- **Biopsy:** After this button is selected, the biopsy guide line will display on the image screen. Some biopsies have different angles to be selected. If this is the case, the system will display the selectable angles for the operator to select from. Different probes feature different biopsy guide lines.
- **VNear:** In the 2D touch panel menu, use the arrow in the "VNear" key to increase or decrease or switch off the level of compounding. When the level is 0, this function is switched off. When the level is 1, 2, 3, one more focus will be added if the position of the current focus is >5 cm. If there are the most focuses, this function doesn't work.

- **NeedleEnhance:** Only works with linear probes. To enhance the needle image when do biopsy. When this function is enabled, a red boundary line will be displayed to show the effective border which should not be crossed, change its angle to match the needle, make sure the angle between the red line and the needle is 90° . The direction can be changed too.
 - **VTissue:** it can automatically calculate the best acoustic velocity in tissue on the basic of the scanning data to improve the image quality. After this button is selected, it will be highlighted to show this function is active. Touch it again to remove this function and the echo speed will return to pre-set one. No "VTissue" in HAR mode.
 - **TI:** Select thermal index display which is one of TIS, TIB and TIC. TIS is the Soft Tissue Thermal Index. TIB is Bone Thermal Index. TIC is Cranial Bone Thermal Index.
 - **SGC (Scanline gain compensation):** Gain compensation for tissue image scan line.
 - **Gain:** Sliding vertically on the left of the image, the overall brightness of 2D image is adjusted. All incoming echoes are amplified with the same digital gain value regardless of the depth. Turning "Gain" control clockwise makes the entire image brighter, and counterclockwise makes the image less bright. The digital gain value is displayed on the screen.
 - **Depth:** Sliding vertically on the right of the image, the depth of the image is changed. This change can only be in real time scan mode.
- Note:
1. Maximum and minimum depth varies according to the different probes used.
 2. Actual depth is displayed in the information header.
- **TGC slides controls:** Adjust TGC can vary the gain in the certain depth of the 2D image.
 - **2D Steer:** Steer the 2D image right direction, center (no steer), left direction. The drawing below is shown as reference. 2D steer only exists in the linear probes.

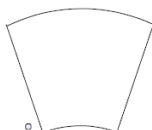
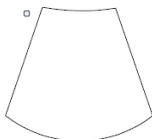


- **2D Automatic Optimization:** This function can optimize the contrast resolution according to the histogram of the scan area. It causes the automatic optimization of the gray scale to enhance the contrast.
- **Harmonic Imaging:** The harmonic imaging reflects the harmonic of the nominal transmitted frequency, such as double, threefold and fourfold. It gives the better grayscale contrast compared to the standard ultrasound imaging.

- **L/R and U/D:** They allow the operator to fold the image from left to right or right to left and up to down or down to up as shown below for reference.



Left/ Right



Up/ Down

- **TView:** Trapezoid view will enlarge the scanning area in order to let the operator see more. For example, the linear probe scanning image is a rectangle, but after this function works, the scanning image will change to a trapezoid which has a larger scanning view in the bottom.
- **Map:** The gray map determines the displayed brightness of an echo. With a different gray map, a harder or softer image can be obtained. Image gray can be adjusted both in the freeze and scan mode. There are 2 kind of map: Gray Map and Tint Map. Operator can select map by touching "<" or ">".

5.1.2 PView

Panoramic view function provides the ability to construct and view a static 2D image which is wider than the field of view of the selected probe. It constructs an extended image from the individual image frames as the operator moves the probe along the surface of the skin.

Operations in PView

1. Touch "PView" to enter "PView" mode.
2. To start acquiring the image, touch "Start". Then move the probe slowly, steadily and in uniform motion lengthwise. Make sure that the probe stays in one plane throughout the scan. The image is stored as you perform the scan and can be monitored during acquisition.
3. To complete the scan, select "Stop".
4. Touch "Reacquisition" to clear the extended image and return to the normal image, and the operator can start again. Selecting the "Exit" on the touch panel goes back to the normal image scan.



The quality and usefulness of the extended images is impacted by the probe motion. The incorrect technique can generate a defective image. A good quality extended image is characterized by the smooth edges and a clear direction. All structures visible in properly scanned 2D images can be easily identified. A poor quality extended image can be recognized by its rough and curved edges. Also, it may contain sections showing noise and defects next to sections of clear structures.

If any poor quality extended image has been generated, the scan has to be repeated and the poor image considered as useless. Any measurement based on a poor image is to be considered not correct. Note that the accuracy of measurement in the extended images is limited and can be lower than measurement on the B images. It is not recommended to use this measurement: be aware that any diagnostic conclusion must not be made based on panoramic image alone and needs to be checked with other diagnostic procedures.

Precaution for uniform motions as follows:

- Make sure that there is enough gel along the scan path.
- Move the probe slowly and steadily.
- It must be ensured that the probe during the acquisition of the extended image always remains in contact with the skin.
- Keep the motion within the same scan plane and do not change the direction of movement during the scan.
- Deeper scanning needs slower motion of the probe due to more data acquisition needed.

5.1.3 Freeze in B/HAR mode

Touch "Freeze" button to enter freeze mode, some parameters will be hidden. Touch the screen, it will display progress bar. There is one triangle blue button. Touch the button, operator can replay the image. Control which frame to start from by drag the process bar.

The frozen image can be optimized by adjusting the parameters or changing the maps when needed.

Note: In Freeze mode, no adjustment is available for the "Frequency", "Focus Position", "Focus #", "Line Density", "VSharpen".

5.2 M Mode

The "M" mode imaging provides the echo information of motion with change of time derived from a stationary ultrasound beam. "M" mode is used along with a 2D image, with one line through the 2D image which is called the "M" cursor. This cursor identifies the position of the ultrasound beam. The motion of the echo information at this position over time is to display "M" mode.

5.2.1 M mode

- **Activation of M mode:** By touching "M", the system goes to "M" mode. M cursor can be moved. 2D and "M" mode stopped by touching "Freeze".
- **Display format:** Operator can change the display format: "H 1/2", "H3/4", "Full", "V2/3", "V1/2", and "V1/3".
- **Dynamic Range:** This allows the operator to enhance the grayscale range to make it easier to display pathology.
- **Acoustic Power:** This can adjust the transmit power by selecting the up/down key.
- **Sweep Speed:** This can adjust the different sweep speeds by touching the left/right arrows on the control panel which matches the relevant touch panel indicator.
- **Gray Filter:** It determines the threshold above which the ultrasound echoes are displayed on the screen in order to suppress the smaller echoes. The Gray Filter value is displayed in the relevant information area on the touch panel.
- **VSharpen:** This allows the existing information easily visible through the digitally processing.
- **Gain:** This can adjust the overall brightness of the "M" mode trace. The adjustment of the "Gain" control determines the amplified amount which applied to the received echoes. "M" gain function only influences the M trace.

5.2.2 Freeze in M mode

After freeze the system, the image will be in the single frame display status. The operator can slide the touch panel horizontally to recall the stored M sequence. By selecting the blue triangle can be changed to the Cine mode. The 2D image will be automatically replayed.

The start frame and end one can be changed in the "B" menu. By sliding the touch panel horizontally, the 2D image can be reviewed frame by frame.

6. CF (Color Flow Mode) / PDI (Power-Doppler Mode)

The Color Flow imaging and Power Doppler imaging uses the Doppler principle to build the image. It gives the information about blood flow velocity, direction, quality and timing. This information is used to overlay a color image onto the 2D grayscale scan image.

6.1 CF mode operation

6.1.1 Main menus of CF mode

- **The activation of CF mode:** Touching "CF" button will activate the "CF" mode. Then, the "CF" box appears in the active 2D image.

Note:

1. The "B/HAR" button is for the operator to switch to "B/HAR" mode parameter change. If "PW" is on, the "PW" button can let the operator switch to "PW/CW" screen for parameter change.
 2. The "PDI" mode does not have an "Invert" button.
- **Flow Speed:** Select different level "Low", "Medium", "High" to adjust the image quality.
 - **Frequency:** This setting controls the transmit frequency. With a higher frequency, the lower flow velocities are displayed better at the given PRF, but the penetration depth is reduced. With a lower frequency, the sensitivity in depth will be increased.
 - **PRF:** The Pulse Repetition Frequency (PRF) governs the displayed velocity range. Increasing the PRF will increase the range of velocity. High PRF will avoid aliasing of blood. However, higher PRF will have a loss of sensitivity to low flow velocities.
 - **Wall Filter:** Wall motion filters are used to eliminate the vessel wall motion and the cardiac motion noise that is low in the velocity and high in the intensity.
 - **Packet Size:** It controls the number of samples gathered for a single color flow vector. This allows the operator to improve the color sensitivity and accuracy of color averaging if increasing the packet size or increase the frame rate if decreasing the packet size.
 - **Color Level:** This function eliminates the small color noise or motion artifact signals.
 - **L/R:** After this button is selected, the image will be folded from left to right and right to left.
 - **U/D:** After this button is selected, the image will be folded from up to down and down to up.
 - **Invert:** This function inverts the color display in relation to the direction of the flow. Normally the red color represents flow to the probe and the blue color represents away from the probe. After inverting, the color will represent different.
 - **Color map:** Those allow the operator to select different color-coding for blood flow display (similar to the post-processing curves with gray scale of B image). Operator can select map by touching "<" or ">".

- **Line density:** It determines the line density within the "CF" box.
- **Sync Display:** After this button is selected, there will be two images on main screen, the left one is 2D image, the right one is 2D+CF image.
- **Persistence:** It smooths the image by performing a temporal averaging which improves the appearance of the color image.
- **Flash Reduction:** It reduces movement artifacts in the image.
- **Line density:** Higher line density will improve the resolution and the reduce frame rate.
- **Base Line:** It can be used to prevent aliasing in one flow direction, similar to the Doppler baseline shift. Shifting baseline will enlarge the velocity range in one direction.
- **Transparency:** Indicates the visibility of background image.
- **Acoustic Power:** It adjusts transmit acoustic power. The higher acoustic power has better penetration.
- **Steer:** Steer the CF image right direction, center (no steer), left direction.

After the system enters frozen mode, sliding on the touch panel horizontally reviews the image frame by frame, similar to the "B" mode.

Note:

1. In Frozen mode, there will be no panoramic view function.
2. Start Frame, End Frame: control which frame to start from and which to end in order to display continuously as a loop.
3. Speed: control cine speed as 400%, 200%, 100%, 60%, 50%, 40%, 20%.
4. In frozen mode, "B" or "PW/CW" mode (if available) can be switched, for adjustment by selecting the mode tabs.

6.1.2 CF box position and size

The ability to change the "CF" mode box size and the position can provide the flexibility in imaging. The box size can be changed by 2 fingers like zoom function in B/HAR mode. And the box position can be changed by touching and moving it with finger.

6.1.3 CF mode gain control

Adjust the "CF" mode digital gain in order to change the sensitivity. If "CF" gain control is too low, it will be difficult to detect the small abnormalities in flow and will possibly result in an underestimation of the large flow disturbances. If "CF" gain control is too high, the noise will be introduced and disturb normal flow detection. So "CF" gain needs to be adjusted properly to ensure continuous flow display, and also be set as high as possible unless the random color speckle appears.

6.1.4 Power Doppler (PDI)

Power Doppler is intended to compensate some deficit of the Color Doppler. Its advantages comparing Color Doppler are less dependent on the incident angle, no aliasing, less dependent on the direction, and sensitive to slow flow.

After "PDI" button is touched, the system will enter "PDI" mode. The layout is similar with the color mode. However, the color bar will have a difference: in the color mode, the color bar has two colors to indicate the flow direction (To probe is red, away from probe is blue), "PDI" color bar does not have the direction information and it indicates the power of flow. "PDI" menu is similar with the color mode. However, all velocity-determined functions are not available in "PDI"; for example, there is no "Invert" button.

The operation of "PDI" is similar to Color Doppler too and can refer to "CF" mode operation.

7. PW mode (Spectral Doppler Mode)

The spectral Doppler describes the Doppler shift signal within a sample volume. It displays scroll from left to right and displays the spectral distribution of Doppler shift frequency over time. The frequency or velocity values appear on the vertical axis and time along the horizontal axis. The strong or weak signal is displayed as varying shades of gray. The strong signals are displayed as bright while the weaker signals are less bright.

7.1 PW mode (Pulsed Wave Doppler)

A sample volume cursor is located on the "PW" cursor and it indicates where, along the ultrasound beam, the spectral analysis is being performed.

Operation of PW mode (main menu)

After "PW" is touched, the system will enter "PW" mode.

- **Flow Speed:** Select different level "Low", "Medium", "High" to adjust the image quality.

Sample volume position and width: In "PW", a specific area along the ultrasound beam is sampled. This is called the sample volume, which is located on the ultrasound beam and is displayed as two lines perpendicular to the beam line. The location and the size of the volume can be changed. The location of sample volume can be adjusted.

- **PW automatic optimization:** To perform the auto optimization, the system will automatically detect the highest flow velocity and adjust the velocity scale (PRF) accordingly in order to display the velocity in full scale properly. At the same time, the baseline will be shifted in order to display the full spectrum.

- **Display format:** Operator can change the display format. In format, there are two kinds of display. One is side by side, while the other one is up and down. In each type of the format, different splits between "B" and "PW" traces displays can be selected. In side by side format, there are three kinds: "H1/2", "H3/4" and "Full". In up and down, there are three kinds: "V2/3", "V1/2" and "V1/3". The "V2/3" display format is as shown below.
- **Invert:** This function inverts the "PW" spectrum display in relation to the direction of flow. The displayed spectrum is inverted around the baseline. The velocity or frequency scale changes accordingly. After "Invert" on the touch panel is selected, this function will work. Spectrum above baseline is the blood flow towards the transducer and spectrum below baseline is the blood flow away from the transducer in normal orientation. In invert status, the orientation will be opposite.
- **Trace Direction:** The operator can also select different trace directions to be "Above", "Below" or both them. "Above" means that the trace will be along the curve of the spectrum above the baseline. "Below" means that the trace will be along the curve of the spectrum below the baseline. Selecting both them means that the trace will be along the curve of the spectrum above and below the baseline. The corresponding evaluation is automatically displayed on the monitor and updated in every heart cycle. There are vertical dotted lines to indicate the latest 1-5 cycle(s), the number of cycle is configured by "Heart Cycle" in PW page. "+" means the peak of the spectrum.
- **Trace Mode:** Operator can select trace mode to be "Max", "Mean", or both them. If none of them is highlighted, auto trace is disabled.
- **Heart Cycle:** 1-5 cycles can be selected.
- **Trace Sensitivity:** Select the trace sensitivity to balance the sensitivity and artifacts. The high sensitivity settings may cause artifacts. The low sensitivity may cause smoothing to some incident events.
- **Acoustic Power:** By pressing "Acoustic Power" on the touch panel can change the transmit power. The high acoustic power output has better penetration.
- **PRF:** The velocity range on display is controlled by the pulse repetition frequency (PRF). As the PRF increases, the velocity measurable range is increased too. As the display scale increases, the maximum Doppler shift information can be increased. The relevant up/down key increases or reduces PRF. Possible the maximum sampling frequency can be automatically adapted based on the sample volume depth. After the certain level of PRF is exceeded, the system is activated into "HPRF" (high PRF mode) mode which can increase the maximum measurable flow velocity further. The normal maximum measurable flow velocity is determined by the measuring depth of the sample volume. In order to further increase measurable

flow velocity to reach the normal limitation, one or more additional sample volumes is added along with the ultrasound beam cursor as the virtual sample volume. The blood flows recorded by the virtual sample volume are overlaying the actual Doppler signal of the main sample volume.

- **Baseline:** The change of "PW" spectrum baseline can enlarge the velocity range in one direction. The displayed velocities or the frequencies on the upper and lower edge of the screen show the maximum measuring velocity range. The up/down key corresponding to baseline can change it up or down.
- **Steer:** PW line can be steered. Only works with linear probes.
- **Angle Correct:** To obtain the optimum resolution and the accuracy from the Doppler measurements, the angle which is between the ultrasound beam and the blood flow should be maintained between 0 and 20 degrees in order to display the vessel in longitudinal section and the angle cursor must be positioned parallel to the vessel axis.
- **Sweep Speed:** The faster sweep speed may be useful to analyze flow curves. Frequency and Wall Filter can be adjusted the same as color mode.
- **Audio Volume:** This allows to change the volume of the audio signal for the "PW" spectrum.
- **Gray Filter:** In order to eliminate low level echoes caused by noise, the operator can adjust this value to remove the certain level of echoes before processing.
- **Dynamic Range:** The "Dynamic range" refers to the compression of the grayscale information into suitable range for the display. It can enhance a certain grayscale range which makes it easier to display pathology. When increasing dynamic range, this will decrease the brightness to more gray shades and less contrast. When decreasing the dynamic range, it will increase the brightness to be less gray shades and more contrast.
- **Spectrum Optimize:** It processes several near-by spectra to optimize spectrum display. The identified number indicates a number of spectra to be processed.

7.2 Freeze in PW

After "Freeze" is touched, the image will be in single frame display status. Operator can replay image by sliding left and right on 2D image. If selecting "Duplex", and touching "Freeze", both the 2D and "PW" image will freeze. At this moment, selecting "2D" button to switch to B menu, operator can replay 2D image.

8. Simple Parameter UI

In “Sys Setting”, if select “Expert” for “Parameter UI theme”, display all parameters, please refer chapter 5-7.

If select “Simple”, the quantity of adjustable parameters will be reduced. Default is “Simple”.

In 2D mode, only display “Image Quality”, “Focus Position”, “Auto”, “Display Format”, “Full Screen”, “Biopsy”, “L/R”, “U/D” and “Center Line”.

In CF mode, only display “Flow Speed”, “Steer”, “Sync Display”, “Full Screen”, “Invert”, and “Baseline”.

In PW mode, only display “Flow Speed”, “Angle Correct”, “Baseline”, “Invert”, “Steer”, “Display Format”, “Sweep Speed”, “Auto” and “Auto Trace”.

In M mode, only display “Sweep Speed” and “Display Format”.

“Steer” is only available with linear probe.

9. Measurement and Calculation

The measurement and calculation results from the ultrasound image can be used to supplement other clinical approaches. Its measurement accuracy depends not only on the system accuracy, but also on the impact of different medical approaches. If necessary, indicate the medical approach relevant to the measurement and calculation. In the meantime, record the details of the researcher and calculation method and database in the system. Refer to the relevant original article as some clinical operation approaches are recommended by researchers.

Note: Before starting an examination, it is normally necessary to input new patient information. Refer to chapter 4. Any measurement can be repeated as long as the measurement is selected again. All the calculation formulas are listed in the Advanced Technical Manual.

9.1 Introduction

This chapter provides system set-up information relevant with measurement. It also introduces what generic measurements are possible and how to make those measurements in each mode. Topics are as follows:

- Measurement workflow
- Position of the measurement key
- Measurement system settings
- General introduction to measurement
- The list of generic measurements in each mode
- How to configure measurement in each mode

9.1.1 Measurement Workflow

For a patient, the system classifies information according to type of examination, category and measurement. These terms are defined as follows:

1. Examination application types which include:

a. Convex:

- Abdominal
- Obstetrics
- Gynecology
- Urology
- Pediatrics
- Nerve Block
- Lung
- FAST
- Abdominal Specific

b. Linear:

- SMP
- Carotid
- Vascular
- Nerve Block
- Pediatrics
- Lung
- Muscle Skeletal
- Breast
- Vascular Specific

c. Phased Array:

- Cardiac
- Pediatrics
- Abdominal
- Lung
- Cardiac Specific
- Specific TCD
- Vessel
- Small organs (e.g. breast, testes, thyroid)
- Trans-cranial Doppler

2. Measurement

This is measurement and calculation for analysis of anatomy, for example, of kidney length. Measurement includes several categories of data. For instance, in order to measure kidney volume, the length, width and height need to be measured.

9.1.2 Measurement system setting

Enter "Sys Setting" menu, and select "Measure", then display setting items as follows:

Cursor

- **Cursor Type:** "+" is the default factory setting for cursor type. Other cursor types can also be selected to replace the factory setting.
- **Cursor Size:** "16x16" is the factory setting. Other size can also be selected for cursor size.
- **Cursor Size When Measure:** "10x10" is factory setting. Other size can be also selected for shape cursor size.
- **Use Arrow Cursor for indication on image:** Enable it and enable "Cursor", there is an arrow on the image.
- **Cursor color of big cross:** Yellow, Lime. The color of the big cursor on PW/M image.

Result Window Setting

- **Show Result Window:** During measurement, results are displayed in the results window with measurement number, and are updated simultaneously until complete. All results are displayed the measurement results window. If necessary, this window can be hidden. Disable "Show RS." button to hide the result window.
- **Window Position:** The position of the measurement result window can be changed. To move the window, select the option from the list below:
 - Top Left
 - Bottom Left
 - Top Right
 - Bottom Right
- **Font Size:** To change the font size in the results window, select the size from the "Font Size" pull-down menu.
- **Keep measure results on result window after unfreeze:** Retain, Clear. If select "Retain", all measurement results of unfinished items are retained, if select "Clear", all measurement results are cleared.
- **Only clear active visual measure results after unfreeze:** The measure results will not be cleared on the visual that is not active after unfreeze the system.

Display

- **Show Cursor line:** During measurement, the system will display one dotted line to indicate measurement. After the position is selected when using touch panel measurement, the system will display measurement line "Enable" is selected for "Show cursor line". If "Disable" is selected, the system will erase the dotted line and only display the caliper with a number. Keep measure lines on replay image: If this function is disabled, the system will erase the dotted line of all measurement when replay one image which contains measurements.
- **Show depth guideline:** Display a dotted line when do the measurement of "Depth". If the probe is linear and "TView" is disabled, the dotted is not needed.
- **Show brief annotation:** Enable it, display brief annotations when do the measurements.
- **Auto adjust cursor size for tiny distance (px):** If the distance is shorter than 10, 20, 30 or 50 pixels, the cursor size will become very small. This function is disabled if select "off".
- **Auto snap range setting (px):** If the measurement method is "Trace", "Polygon" or "Spline", when the distance between the end point and the start point is shorter than 10, 20, 30 or 50 pixels, the measurement will finish automatically, and the last cursor back to the start point. This function is disabled if select "off".
- **Annotation font size:** To change the font size of the annotation, select the size from the "Annotation font size" pull-down menu.
- **Show result of protocol items in worksheet:** If the current measurement is multi-step (like "Volume- L&W&H"), before finish the measurement, enter "Worksheet", this measurement item will be displayed. This function is disabled if select "off".
- **Show comment of measure item:** Explain the measurement item in local language.
- **Unit for normal distance related measurement:** cm, mm. Select different unit for normal distance measurement. Length measurement unit for high resolution probe: mm, cm, inch, ft. Select different unit for length measurement unit of high-resolution probe.
- **Unit for area related measurement:** m2, cm2, mm2.
- **Unit for velocity related measurement:** m/s, cm/s, mm/s. Unit for time related measurement: s, ms.
- **Worksheet Statistic Method:** Avg, Min, Max, Last.
- **Auto calculation mode:** Not support, Support, Support (Only display latest calculation results). Measure across multiple images: In dual or quad display format, the measure lines can across the image A and B or image C and D if this function is enabled. But the lines cannot across the image A and C or image B and D.

- **Show absolute value for velocity in Doppler mode:** No minus value of velocity if this function is enabled.

OB Measure Global Config

- **Show GA(LMP/BBT) on status bar:** If there is GA(LMP/BBT) for the current patient, display it on the status bar.
- **Show GA after Measure:** During measurement, select whether or not to display the estimated fetal age automatically. If the fetal age is selected to be displayed in system set-up, the measurement results window will display estimated age after a measurement. If not, the estimated age will not be displayed in the results window.
- **Add 1 week to EDD Calc:** If this item is selected, delivery time will be increased by 1 additional week.
- **Show EDD after Measure:** During measurement, select whether or not the estimated delivery time is displayed automatically after measurement. If estimated delivery time display is selected in the system setting, the estimated delivery time will appear in the results window after measurement. If not, estimated delivery time will not appear in the results window.
- **Show Percentile after Measure:** Enable it, after finish the OB related measurement, show the percentile according to the OB table. LMP, BBT or GA need to be input when create the current patient before do the measurement.
- **Auto Select EFW Method:** Enable it, the system will select EFW method automatically when do EFW related measurements.
- **Auto Generate Fetal Growth Curve Graph When Enter Report:** Fetal growth curve graph will be generated automatically when enter report if this function is enabled.
- **GA Display Format:** To change the display format for "GA" after enable "Show GA after measure".
- **EFW Method:** According to different areas select different methods.
- **Unit for EFW:** auto, g, kg, lb/oz. The unit of EFW is depended on the EFW method if "auto" is selected.
- **OB Table Type:** According to different area select different types.
- **OB Measure Item GA Table Config:** To configure GA table for every measurement item.
- **User Defined OB Tables:** User defined OB tables can be imported, deleted. Plug in one USB device, there is one file folder named "OBTables" in USB device, in the folder the file named "FG Table Template.csv" or "GA Table Template.csv" can be imported. Folder name and file name should be the same as the described above.

Table Example:

| Table Category | Measured Item | Author Name | Table Range | Measured Value Unit | GA Unit | SD Unit |
|----------------|----------------|-------------|-------------|---------------------|---------|---------|
| GA | CRL | bbb | 2 | mm | day | Day |
| Index | Measured Value | GA Min | GA Mean | GA Max | GA SD | |
| 1 | 50 | | 79 | | 22 | |
| 2 | 55 | | 82 | | 22 | |
| 3 | 60 | | 85 | | 22 | |
| 4 | 65 | | 89 | | 22 | |
| 5 | 70 | | 92 | | 22 | |
| ... | ... | ... | ... | ... | ... | ... |

9.1.3 Basic introduction in measurement function

Touch "Measure"  the system will enter measurement mode.

Notes:

- To stop image acquisition before measurement, touch "Freeze".
- To adjust accuracy of caliper, move the cursor.
- To delete the caliper and measurement data before complete sequence measurement, clear it.
- To repeat the measurement, select the relevant measurement item on the touch panel.

Notes:

After enter "Measure", the system will go to the default measurement setting in the relevant application. For example, in "B"/ "M" mode, the default measurement is "Distance". Default measurement is "Velocity" in the PW mode.

Measurement erasing


Measurement results can be deleted from system memory as follows:

- After the image is unfreeze, the system will erase all displayed completed measurement results, calculation results and result window. However, measurement and calculation results will be kept in the worksheet.
- If "New Patient" is selected, the system will erase all measurement results, calculation results, and worksheet.

Measurement results worksheet

After the measurement is completed, all effective measurement results will be entered on the worksheet automatically.

In measure page, touch "Worksheet", then select different applications, the system will display all measurement results.

- **1/2/3:** This is for repeating measurements of the same item. The maximum is 5 times. If the number of repeated measurements exceeds 5, the worksheet will only save the last 5 measurement results.
- **Avg:** This is for post-processing method of measurement results. The options are: Average, Minimum, Maximum and Last. The desired method is selected from the pull-down menu by selecting the relevant position. 1 is for all items, 2 is for the related item.
- **Unit:** The unit of measurement value and displayed result. The operator can select different units by touching the unit.
- **Print:** Print the worksheet by the selected printer.
If there are more than one printer connected with this device, touch printer button to choose one printer. Touch ">" to configure printer's setting.
- **Edit:** Button "Edit"  is selected, the operator can change the unit and statistics, and change the method of EFW. If the data is highlighted, it is selected for calculating Average, Minimum and etc., and it will appear in the report.

The first three items "LMP", "GA(LMP)" and "EDD(LMP)" are from patient information, and the rest items are calculated by the measurement results. If there is more than one fetus, other fetuses' information will be listed here too.

9.1.4 Generic measurement list in each mode

9.1.4.1 B Mode Generic Measurement

There are 8 generic measurements in 2D mode

- Depth
- Distance
- Perimeter
 - Length and Width method
 - Ellipse method
 - Polygon method
 - Spline method
 - Tracing method
- Area
 - Length and width method
 - Ellipse method

- Polygon method
- Spline method
- Tracing method
- Volume
 - Single line method
 - Dual line method
 - Triple line method
 - Single ellipse method
 - Single ellipse and single line method
- Angle
- Stenosis
 - Diameter method
 - Square meter method
- A and B ratio
 - Diameter ratio
 - Square meter ratio

Note: Enter "Measure" the system will enter frozen mode automatically.

Depth measurement:

The steps are as follows:

1. Enter "Measure": one caliper will be displayed on the image screen.
2. Move the caliper to measurement menu to select "Depth" category.
3. Move the caliper position.
4. After moving the cursor to the position for measurement, confirmation it.
5. The system will display depth in the measurement results window.

Distance Measurement:

The steps are as follows:

1. Enter "Measure".
2. Select the "Distance" measurement category if current measurement is not.
3. Move caliper to the measurement start point.
4. Confirm start point. The system will fix one caliper and a second caliper appears.
5. Move the second caliper to the end point.
6. Confirm the end point to complete the distance measurement.

Perimeter: Length and width method

Perimeter can be measured by two distances (length and width). The steps are the process of the measurement as follows:

1. Enter "Measure".
2. Select "Perimeter" in the measurement menu.
3. Select "L&W" approach in the perimeter menu. Caliper will display on the image screen
4. Measure the two distances separately.
5. After the two distance measurements are complete, the system will display perimeter in the measurement results window.

Perimeter: Ellipse method

Perimeter can be measured by ellipse. The steps are the process of the measurement as follows:

1. Enter "Measure".
2. Select "Perimeter" in the measurement menu.
3. Select "Ellipse" approach in the perimeter menu. A caliper will display on the image screen
4. Position the first point. The system will fix the first caliper and display the second caliper.

5. Position the second point and confirm it. The system will display the third caliper and trace the ellipse shape.
6. Finalize the third caliper and ellipse.
7. Measurement results window will display perimeter result.

Perimeter: Polygon method

Perimeter can be measured by a polygon. The steps are the process of the measurement as follows:

1. Enter "Measure".
2. Select "Perimeter" in the measurement menu.
3. Select "Polygon" approach in the perimeter menu. Caliper will display on the image screen
4. Fix the first caliper and the second caliper appears.
5. Fix the second caliper and display the third caliper and trilateral trace.
6. Fix the third caliper and display the fourth caliper and quadrilateral.
7. Fix the fourth caliper and display the fifth caliper and pentagon.
8. The rest can be done in the same manner in order to complete measurement in any polygon method. After the measurement is completed, the results window will display the result.

Perimeter: Spline method

Perimeter can be measured by spline. The steps are the process of the measurement as follows:

1. Enter "Measure".
2. Select "Perimeter" in measurement menu.
3. Select "Spline" approach in the perimeter menu. Caliper will display on the image screen.
4. To move the first caliper to the start point.
5. Fix the first caliper and the second caliper appears in the same position as the first caliper position.
6. Fix the second caliper, the third caliper will appear in the same position.
7. Fix the final caliper.
8. After measurement is completed, the results window will display the result.

Perimeter: Tracing method

Perimeter can be measured by tracing method. The steps are the process of the measurement as follows:

1. Enter "Measure".

2. Select "Perimeter" in the measurement menu.
3. Select "Tracing" approach in the perimeter menu. Caliper will display on the image screen
4. Move the first caliper.
5. Fix the start point. Tracing caliper will change to an activated caliper.
6. Trace the anatomical structure of the measurement field. The tracing curve will change to a dotted line.
7. Complete measurement, the results window will display the perimeter result.

Area measurement: Length and width method

Area can be measured by length and width. The steps are as follows:

1. Enter "Measure".
2. Select "Area" in the measurement menu.
3. Select "L&W" method in the area measurement menu. The active caliper will display on the image screen
4. Measure the two distances in sequence.
5. After the two distance measurements is completed, the area result will display in the result window.

Area measurement: Ellipse method

Area can be measured by ellipse. The steps are as follows:

1. Enter "Measure".
2. Select "Area" in the measurement menu.
3. Select "Ellipse" method in the area measurement menu. The active caliper will display on the image screen
4. Fix the start point; then the second caliper is displayed.
5. Fix the second point and third caliper and ellipse shape display.
6. Fix the third point to complete the measurement.
7. Results will display in the results window.

Area measurement: Polygon method

Area can be measured by polygon. The steps are as follows:

1. Enter "Measure".
2. Select "Area" in the measurement menu.
3. Select "polygon" method in the area measurement menu. The active caliper will display on the image screen
4. Fix the start point, then the second caliper is displayed.
5. The rest can be done in the same manner, and any polygon can be used to measure area. After measurement is complete, the system will display the results in the results window.

Area measurement: Spline method

Area can be measured by spline. The steps are as follows:

1. Enter "Measure".
2. Select "Area" in the measurement menu.
3. Select "Spline" method in the area the measurement menu. The active caliper will display on the image screen
4. After the first caliper is fixed, the second active caliper is displayed in the same position as the first caliper.
5. The rest can be done in the same manner.
6. After the measurement is completed, the results window will display the result.

Area measurement: Tracing method

Area can be measured by tracing. The steps are as follows:

1. Enter "Measure".
2. Select "Area" in the measurement menu.
3. Select "Tracing" method in the area measurement menu. The active caliper will display on the image screen
4. Move the caliper to the target position.
5. Fix the start point. The active caliper will display in the screen.
6. Trace the measurement dotted line along which the anatomy needs to be measured.
7. After the tracing is completed. Then the result will display in the results window.

Volume measurement

Volume can be measured by one of the approaches as follows:

- Single line (L), i.e. single distance method
- Dual line (L&W), i.e. dual distance method
- Triple line (L&W&H), i.e. triple distance method
- Single ellipse
- Single ellipse and single line method

Refer to "Distance" measurement to know how to measure distance for details.

Refer to "Perimeter" and "Area" measurement to know how to measure ellipse for details.

To measure volume through single or dual distance method, the steps are as follows:

1. Enter "Measure".
2. Select "Volume" in the measurement menu.
3. Select "L" or "L&W" method in the volume measurement menu. The active caliper will display on the image screen
4. Proceed with single or dual distance measurement.
5. The result will display in the results window.

To measure volume by triple distance method, the steps are as follows:

1. Enter "Measure".
2. Select "Volume" in the measurement menu.

3. Select "L&W&H" method in the volume measurement menu. The active caliper will display on the image screen
Notes: Triple distance can complete in dual image display format. First measurement normally is done in midsagittal plane.
4. Proceed with single distance and dual distance measurement.
5. Volume result is displayed in the results window.

To measure volume by ellipse method, the steps are as follows:

1. Enter "Measure".
2. Select "Volume" in the measurement menu.
3. Select "Ellipse" method in the volume measurement menu. The active caliper will display on the image screen
4. Proceed with ellipse measurement
5. Volume result is displayed in the results window.

To measure volume by ellipse and single distance method, the steps are as follows:

1. Press "Measure"
2. Select "Volume" in the measurement menu.
3. Select "Ellipse&H" method in the volume measurement menu. The active caliper will display on the image screen
Note: Single ellipse and distance can be measured in dual display format. The first measurement normally proceeds in midsagittal plane. The second measurement proceeds in the axial plane normally. Press "Left" or "Right" to activate dual display format.
4. Proceed with single distance and ellipse measurement.
5. Volume result is displayed in the results window.

Notes:

To change parameters during volume measurement, the steps are as follows before restarting measurement.

1. Check every item's measurement result in the results window.
2. If data is not accurate or blank, select editing of relevant measurement or relevant menu in the bottom, then measure and calculate again.

Reminders:

- Result is most accurate in midsagittal plane and axial plane measurement.
- To display midsagittal plane and axial plane simultaneously, use dual display format.

Angle Measurement

The steps are as follows:

1. Enter "Measure".

2. Select "Angle" in the measurement menu. The active caliper will display on the image screen
3. Move the caliper.
4. Fix the first caliper and the second caliper will display.
5. Move the second caliper to desired position.
6. Fix the second caliper and third caliper will display.
7. Move the third caliper to the desired position.
8. Fix the fourth caliper. The result is displayed in results window.

Stenosis: Diameter stenosis can be calculated by diameter or area approaches.

Diameter

Note: After using diameter approach to calculate stenosis, do not measure distance in vertical angle. It can result in inaccurate estimation of stenosis. It is better to measure vessel diameter in the cross-sectional perspective.

The steps are to calculate stenosis by diameter approach as follows:

1. Enter "Measure".
2. Select "Stenosis" in the measurement menu.
3. In the stenosis measurement menu, after the "Diam" approach is selected, an active tracing caliper will display on the image screen
4. Measure the inter-vascular distance. The system will display another caliper for second distance measurement.
5. Measure the distance of exterior vessels.
6. The results window will display each measured distance and stenosis percentage.

Refer to the distance measurement to know how to measure distance.

Area

The steps are to calculate stenosis by area approach as follows:

1. Enter "Measure".
2. Select "Stenosis" in measurement menu.
3. In "Stenosis" measurement menu, after "Area" approach is selected, an active tracing caliper will display on the image screen
Notes: Different area measurement approaches can be selected (such as length & width, ellipse, polygon, spline, and tracing method)
4. Measure the area of inter vascular. The system will display another active caliper for second area measurement.
5. Measure the area of the exterior vessel.
6. Results window displays two area results and stenosis percentage. Refer to the area measurement to know how to measure area.

A and B rate

In B mode, A and B ratio can be calculated by diameter or area measurement.

Diameter

The steps are to calculate A and B ratio by diameter measurement as follows:

1. Enter "Measure".
2. Select "A/B ratio" in the measurement menu.
3. In the "A/B ratio" measurement menu, select the "Diam" approach and an active tracing caliper will display on the image screen
4. Measure the first diameter distance. The system displays another caliper for the second distance measurement.
5. Proceed with the second distance measurement.
6. The system will display two distance measurement results, A and B ratio. First diameter is A and second diameter is B.

Refer to the distance measurement for details on the distance measurement approach.

Area

The steps are to calculate A and B ratio by area measurement as follows:

1. Enter "Measure".
 2. Select "A/B ratio" in the measurement menu.
 3. In the "A/B ratio" measurement menu, select the "Area" approach and an active caliper will display on the image screen
Note: Here, different area measurement methods (length & width, ellipse, polygon, spline, and tracing method) can be selected.
 4. Proceed with area A measurement. The system will display another active caliper for second area measurement.
 5. Proceed with area B measurement.
 6. The system will display two area measurement results and the A/B ratio in result window. Refer to the area measurement section for details on the area measurement approach.
- Besides these 8 items there is another measure item "Curve Length". It has 3 methods: Spline, Trace, Polygon.

9.1.4.2 M mode measurement

There are 7 generic measurements in M mode:

- Depth
- Distance
- Time
- Speed
- Heart rate
- Stenosis
- A and B ratio
 - Diameter ratio

- Time ratio
- Speed ratio

Note:

There are the following assumptions before proceeding with measurement:

1. The image screen is displaying anatomy to be measured.
2. System is in M mode. (If not, enter M mode).
3. The system is in "Frozen" state. (If not, press "Freeze").

Anatomic Depth Measurement

M mode anatomic depth measurement is the same as B mode. It measures the depth between the measured point and the top of image, the steps are as follows:

1. Press "Measure" once: A vertical and horizontal dotted line and an active tracing caliper will display on the image.
2. Position the depth to be measured.
3. Finalize the position.
4. The depth result will be displayed in the results window.

Distance measurement

The same as "B" mode in distance measurement. It measures the distance between two calipers. The steps are as follows:

1. Enter "Measure".
2. Select "Distance" in the measurement menu. A vertical and horizontal dotted line and an active tracing caliper will display on the image screen.
3. Move the caliper to start point.
4. Finalize the start point. The system will display the second active caliper.
5. Position the second measurement point.
6. Complete measurement
7. The distance result will be displayed in the results window.

Time interval measurement

M mode time interval measurement is to measure horizontal interval between two calipers. The steps are as follows:

1. Enter "Measure".
2. Select "Time" in the measurement menu. A vertical and horizontal dotted line and an active caliper will display on the image screen
3. Move caliper to the measurement start point.
4. Finalize start point. The system will display a second active caliper.
5. Position the second measurement point.
6. Complete measurement. The time interval result will be displayed in the results window.

Speed measurement

In M mode, use the slope between two points to gain the speed of the two points. The steps are as follows:

1. Enter "Measure".
2. Select "Slope" in the measurement menu. A vertical and horizontal dotted line and an active caliper will display on the image screen.
3. Move the caliper to measurement start point.
4. Finalize the start point. The system will display a second active caliper.
5. Position the second measurement point.
6. Complete measurement. The system will display the speed between the two points.

Heart Rate measurement

Heart rate can be calculated in M mode. The steps are as follows:

1. Press "Measure" in the desired image.
2. Select "HR" in the measurement menu. A vertical and horizontal dotted line and an active caliper will display on the image screen.
3. Position one identifiable point in one heart cycle.
4. Fix the first point. The system will display the second caliper.
5. Move the caliper to the same position as the first one in the second cycle.

Note:

- The number of measured cycles can be selected in the HR menu, from 1 to 5.
 - The number of required measurement cycles is displayed in the information bar at the bottom of the screen.
6. Complete measurement and transfer the calculation into the worksheet. The system will display heart rate in the results window.

Stenosis measurement

The stenosis measurement in M mode is the same as diameter measurement method in 2D mode. It measures the percentage between two distances. The steps are as follows:

1. Enter "Measure".
2. Select "Stenosis" in the measurement menu. A vertical and horizontal dotted line and an active caliper will display on the image screen.
3. Measure the distance in the inter-vessel area. The system will display another active caliper.
4. Proceed with the distance in the exterior vessel area.
5. The system will display each distance and stenosis percentage in the results window. Refer to the distance measurement for details.

A and B ratio

In M mode, A and B ratio can be measured through diameter, time and speed measurement.

Diameter

Calculate A and B ratio through diameter approach, the steps are as follows:

1. Enter "Measure".
2. Select "A/B ratio" in the measurement menu.
3. Select "MDiam" measurement approach in the A/B ratio menu.
4. Perform two distance measurements.
5. The system will display each distance, and the A/B ratio. Note: The first distance is A and the second distance is B. Refer to the distance measurement for details.

Time

Calculate A and B ratio through time, the steps are as follows:

1. Enter "Measure".
2. Select "A/B ratio" in the measurement menu.
3. Select "Time" measurement approach in A/B ratio menu.
4. Perform two times interval measurements.
5. Complete measurement, the system will display two measured time results, A and B ratio.

Speed

The steps are as follows:

1. Enter "Measure".
2. Select "A/B ratio" in the measurement menu.
3. Select "Velocity" measurement approach in A/B ratio menu.
4. Perform two speed measurements.
5. Complete measurement, the system will display two measured time results, A and B ratio.

9.1.4.3 PW mode measurement

There are 19 types of measurement in "PW" mode:

- Speed (include PV (Peak Velocity))
- Time (include AT (Accelerate Time))
- Acceleration
- PS (Peak Speed in systole period)
- ED (The speed in the end of diastole period)
- MD (Minimum speed in diastole period)
- TAMAX (maximum speed in time average)
- TAMEAN (mean speed in time average)
- PI (Pulsatility Index)
- RI (Resistance Index)
- PS and ED ratio
- ED and PS ratio
- A and B ratio (A/B ratio)
 - Speed ratio
 - Time ratio
 - Acceleration ratio

- FLOWVOL (Flow Volume)
- MaxPG (maximum pressure gradient)
- MeanPG (Mean pressure gradient)
- SV (Stroke Volume)
 - Each volume diameter cardiac
 - Time mean speed in each stroke volume
- Heart rate

Note:

To carry out this operation:

1. Scan vessel to be measured in B or B plus CF mode.
2. Turn to "PW" image.
3. Touch "Freeze" button.

Speed, Time Interval and Acceleration Measurement

Speed (cm/s or m/s)

In PW mode, the steps of proceeds with speed measurement are as follows:

1. Enter "Measure".
2. Select "Velocity" in the measurement menu.
3. Move the caliper to position the speed measurement point, and fix it.
4. The result will be displayed in the results window.

Time interval

The steps are as follows:

1. Enter "Measure".
2. Select "Time" in the measurement menu.
3. Position the first measurement point.
4. After position is fixed, the system will display the second caliper.
5. Position the second measurement point.
6. Complete the measurement, the system will display time interval between two calipers in the results window.

Acceleration (m/s²)

The steps are as follows:

1. Enter "Measure".
2. Select "Acceleration" in the measurement menu.
3. Position the first measurement point.
4. Once position is fixed, the system will display the second caliper.
5. Position the second measurement point.
6. Complete the measurement, the system will display the acceleration between two points and the time interval result in the results window.

PS (Peak speed in systole period), ED (The speed in the end of diastole period) and MD (Minimum speed in diastole period) measurement

The steps are as follows:

1. Enter "Measure".
2. Select PS, ED or MD in the measurement menu.
3. Move the caliper to position the measurement point
4. Complete measurement. The system will display peak speed in systole period, the speed in the end of diastole period and the minimum speed in diastole period.

TAMAX, TAMEAN measurement

The steps are as follows:

1. Enter "Measure".
2. Select TAMAX, TAMEAN in the measurement menu. A live tracing caliper will display on the image screen.
3. Move the caliper to position the start measurement point.
4. Fix the start point.
5. Move the caliper to trace spectrum in maximum, mean or minimum.
6. Complete the measurement. The result will be displayed in the results window.

PI (Pulsatility Index) measurement

The steps are as follows:

1. Enter "Measure".
2. Select "PI" in the measurement menu.
3. Move the caliper to position the start measurement point.
4. Fix the start point. The second caliper will display in the system.
5. Move the caliper to trace the whole wave.
6. Complete the measurement. The system will display results of peak speed in systole period, minimum speed of diastole period, the speed of the end of diastole period, TAMAX and PI in results window.

Resistance index (RI) measurement

In "PW" mode, PI can be calculated by ED or MD measurement.

By ED measurement

The steps are as follows:

1. Enter "Measure".
2. Select "RI" in the measurement menu.
3. In the "RI" setting menu, select "ED" method.
4. Move the caliper to position the start measurement point in peak speed of systole period.
5. Fix the start point. Second caliper will display in the system.
6. Position the second caliper in the end of diastole period.
7. Complete the measurement. The system will display PS, ED and RI in the results window.

Through MD measurement

The steps are as follows:

1. Enter "Measure".
2. Select "RI" in the measurement menu.
3. In the "RI" setting menu, select "MD" method.
4. Move the caliper to position the start measurement point in peak speed of systole period.
5. Fix the start point. Second caliper will display in the system.
6. Position the second caliper in the minimum diastole speed.
7. Complete the measurement. The system will display PS, ED and RI in the results window.

PS and ED or ED and PS ratio

To calculate PS and ED or ED and PS ratio, the steps are as follows:

1. Enter "Measure".
2. Select "PS/ED" or "ED/PS" in the measurement menu.
3. Position the caliper in systole peak speed (PS) or diastole end speed (ED).
4. Fix point. Second caliper will display.
5. Position the second caliper in diastole end speed (ED) or systole peak speed (PS).
6. Complete the measurement. The system will display PS, ED and PS/ED or ED/PS ratio in result window.

A and B ratio

In PW mode, A and B ratio can be measured through speed, time or acceleration.

Speed

Calculate A and B ratio through speed, the steps are as follows:

1. Enter "Measure".
2. Select "A/B ratio" in measurement menu.
3. In the "A/B ratio" setting menu, select "Velocity" method.
4. Perform two speed measurements.
5. Complete the measurement. The system will display two speed results and A/B ratio in the results window.

Time

Calculate A and B ratio through time, the steps are as follows:

1. Enter "Measure".
2. Select "A/B ratio" in the measurement menu.
3. In the "A/B ratio" setting menu, select "Time" method.
4. Perform two times interval measurements.
5. Complete the measurement. The system will display two times results and A/B ratio in the results window.

Acceleration

Calculate A and B ratio through acceleration, the steps are as follows

1. Enter "Measure".
2. Select "A/B ratio" in the measurement menu.
3. In the "A/B ratio" setting menu, select "Acceleration" method.
4. Perform two acceleration measurements.
5. The system will display two acceleration results and A/B ratio in the results window.

FLOW VOL (Flow volume)

The steps are as follows:

1. Enter "Measure".
2. In the normal Doppler measurement menu, select "FLOWVOL".

Max PG (maximum pressure gradient)

The steps are as follows:

1. Enter "Measure".
2. In the normal Doppler measurement menu, select "Max PG".

Mean PG (mean pressure gradient)

The steps are as follows:

1. Enter "Measure".
2. In the normal Doppler measurement menu, select "Mean PG".

SV Diam (Stroke volume diameter)

The steps are as follows:

1. Enter "Measure".
2. In the normal Doppler measurement menu, select "SV".
3. Select "SV Diam" in the SV menu

SV TAMEAN (stroke volume TAMEAN)

The steps are as follows:

1. Enter "Measure".
2. In the normal Doppler measurement menu, select "SV".
3. Select "SV TAMEAN" in the SV menu.

Heart rate measurement

In PW mode, heart rate can be calculated, the steps are as follows

1. Press "Measure" after gain image.
2. Select "HR" in the measurement menu.
3. Position an identifiable point in the first heart cycle.
4. Fix the first caliper. The system will display the second caliper.
5. Move the second caliper to be the same position as the first one in the second heart cycle.

Note:

- Set required heart cycles for measurement in the "HR" menu. Heart cycle range from 1 to 5.
 - In the bottom information bar of the image screen, the system will display the number of heart rate which needs to be measured.
6. Complete measurement and transfer to worksheet in the meantime. The system will display "HR" in the result window.

Auto Trace

To execute "Auto Trace", the steps are as follows:

1. Enter "Measure".
2. In the normal Doppler measurement menu, select "Auto Trace".
3. Touch on PW image.
4. The system will provide the results automatically. And there are vertical dotted lines to indicate the latest 1-5 cycle(s), the number of cycle is configured in config page. "+" means the peak of the spectrum.

Semiauto Trace

To execute "Semiauto Trace", the steps are as follows:


1. Enter "Measure".
2. Select item "Semiauto Trace".
3. Fix the start and end point on PW image.
4. The system will provide the results automatically. And there are vertical dotted lines to indicate the valid cycle(s).

Manual Trace

To execute "Manual Trace", the steps are as follows:

1. Enter "Measure".
2. Select item "Manual Trace".
3. Fix the start point, move the caliper to trace the spectrum.
4. Move the caliper on PW image back to start point, delete the trace line.
5. Fix the end point. The system will provide the results.

9.1.5 Measurement Configuration

Select  to enter configuration page.

- **Config Groups:** Display all groups, select one or more groups, select "v", the selected groups will be added to measurement menu. Unselect one or more groups, they will be removed from measurement menu.
- **Config Folders:** Display all folders, different applications or modes have different folders. Select one or more folders, select "v", the selected folders will be added to measurement menu. Unselect one or more folders, they will be removed from

measurement menu. There is only one folder in some applications, it will be "General".

- **Config Items:** Select one item, if it has more than one method, the system will enter change method page, the operator can select different methods or target items here. Selected methods will be used after back to measurement menu, and selected target items will display in the result window. Select and hold on one item, move it to the first position, then this item is set to be the default one.
- **Add/Remove:** Select the desired measurement items, select "Save" or "v", the system returns to the measurement menu and all selected items are displayed. The unselected items will be removed.

9.2 Abdominal Measurements

Brief introduction:

Based on different applications, abdominal measurement provides several different types of measurement options:

- General abdomen
- Difficult abdomen
- Kidney
- Renal vessel
- Abdominal trauma

9.2.1 2D Mode Measurements

The measurement menu in the "Abdominal" application includes generic measurement and specific measurement, such as aorta diameter, renal length, and renal volume.

In 2D mode, generic measurement in abdominal application covers the following criteria:

- Depth
- Volume
- Angle
- Stenosis
- A and B ratio

Refer to the 8.1.4 for more detail on those measurements.

In 2D mode, specific measurements in the abdominal application include the following items:

Aorta Diameter

Aorta diameter can be measured by single distance measurement. The steps are as follows:

1. Enter "Measure".
2. Select "Aorta Diameter", then a caliper will display on the image screen
3. Position the caliper in the start point.
4. Fix the start point. The second active caliper will display.
5. Position the second caliper in the end point.

6. Complete the measurement. The system will display the aorta diameter result in the results window.

Renal Length

Renal length can be measured by single distance measurement. The steps are as follows:

1. Enter "Measure".
2. Select certain direction of Renal Length (left or right), then a caliper will display on the image screen
3. Position the caliper in start point.
4. Fix the start point. The second active caliper will display.
5. Position the second caliper in the end point.
6. Complete the measurement. The system will display the renal length result in the results window.

Renal Volume

Renal volume is normally measured by the three-distance method. The steps are as follows:

1. Enter "Measure".
2. Select a certain direction of Renal Volume (left or right), and then a caliper will display on the image screen
Note: Three distances can be measured in the dual image display format. The first measurement can be processed in the midsagittal plane, and the second measurement can be processed in the axial plane.
3. Proceed with the single and dual distance measurement.
4. The system will display three distances and the renal volume result in the results window.

Spleen volume

Spleen volume is normally measured by the three-distance method. The steps are as follows:

1. Enter "Measure".
2. Three distances can be measured in the dual image display format. The first measurement can be processed in the midsagittal plane, and the second measurement can be processed in the axial plane.
3. Proceed with the single and dual distance measurement.
4. The system will display three distances and the spleen volume result in the results window.

Bladder volume

There are 2 methods to measure bladder volume: Manual and Auto.

Manual method:

1. Press "Measure" key.
2. Select "Bladder Volume", and then a caliper will display on the image screen
Note: Three distances can be measured in the dual image display format. The first measurement can be processed in the midsagittal plane, and the second measurement can be processed in the axial plane.
3. Proceed with the single and dual distance measurement.
4. The system will display three distances and the bladder volume result in the results window.

Auto method:

1. Press "Measure" key.
2. Select "Bladder Volume" measurement.
3. Select "Auto".
4. Touch on the image.
5. Unfreeze the system, change scanning section, enter measure again, and touch the image.
6. The system will get the result of bladder volume automatically.

Prostate volume

Prostate volume is normally measured by the three-distance method. The steps are as follows:

1. Enter "Measure".
2. Select Prostate, and then a caliper will display on the image screen.
Note: Three distances can be measured in dual image display format. The first measurement can be processed in the midsagittal plane, and the second measurement can be processed in axial plane.
3. Proceed with the single and dual distance measurement.
3. The system will display three distances and the prostate volume result in the results window.
4. The measurement items can be added to or removed based on each operator's measurement requirements. Refer to the measurement configuration for how to set measurements in detail.

9.2.2 M mode measurements

In M mode, the measurement menu includes these measurement items:

- Stenosis
- A and B ratio
- Heart Rate

Refer to the Generic measurement in detail for those measurements.

Measurement items in the measurement setting menu can be added to or removed based the operator's requirements. Refer to measurement configuration information in detail.

9.2.3 PW mode measurements

In "PW" mode, the measurement menu includes these measurement folders:

- Generic measurement folder
- Aorta measurement folder
- Common hepatic artery measurement folder
- Renal artery measurement folder
- Renal vein measurement folder
- Postcava measurement folder
- Superior mesentery artery measurement folder

Increase or reduce measurement items in the measurement setting menu based on their own requirement. Refer to measurement configuration in detail.

Generic measurement folder

In "PW" mode, the generic measurement folder includes items as follows:

- Velocity
- PS (systole peak speed)
- ED (diastole end speed)
- MD (Minimum speed in diastole period)
- TAMAX (maximum speed in time average)
- PI (Pulsatility index)
- RI (Resistance index)
- PS/ED
- ED/PS
- A/B ratio
 - Velocity
 - Time
 - Acceleration
- HR

Refer to the Generic measurement in detail for those measurements.

Increase or reduce measurement items in the measurement setting menu based on their own requirement. Refer to measurement configuration in detail.

Measurement folder for other anatomic structure

In "PW" mode, other measurement folders based on an atomic structure include measurement items as follows:

- Velocity
- PS (systole peak speed)
- ED (Diastole end speed)
- PI (Pulsatility index)
- RI (Resistance index)

Add or remove measurement items in the measurement configuration menu based on requirements.

9.3 Small Organ Measurements

Brief introduction

Based on different applications, small organ measurement provides several different measurement options:

- Thyroid
- Breast
- Testis
- Musculoskeletal
- Upper and lower extremity joint
- Nerve block

9.3.1 2D mode measurements

The small organ application measurement menu includes generic measurement and specific measurement, such as length of thyroid isthmus, thyroid, volume, testis volume, etc.

In 2D mode, generic measurement in small part application includes measurement items as follows:

- Distance
- Volume
- Stenosis

Refer to the generic measurement for more details.

In 2D mode, the specific measurement in small part application includes measurement items as follows:

Length of thyroid isthmus

Length of thyroid isthmus can be measured by a single distance. The steps are as follows:

1. Enter "Measure".

2. Select "AP" (Length of thyroid isthmus), and an active tracing caliper will display on the image screen.
3. Position the caliper at the start point.
4. Fix the start point. The second caliper will display on the image screen.
5. Position the end point. If it has a relevant system measurement preset, a dotted line connects the two measurement points.
6. Complete the measurement. The system will display length of thyroid isthmus in the results window.

Thyroid volume

Thyroid volume is normally measured by the three distances method. The steps are as follows:

1. Enter "Measure".
2. Select proper direction (left or right) Thyroid Volume. An active tracing caliper will display on the image screen
Note: The three distances can be measured in the dual image display format. First measurement can be processed in the midsagittal plane, and the second measurement can be processed in axial plane.
3. Proceed with the single and dual distance measurement.
4. The system will display distance and thyroid volume in the results window.

Testicle Volume

Testicle volume is normally measured by the three distances method. The steps are as follows:

1. Enter "Measure".
2. Select proper direction (left or right) Testicle Volume. An active tracing caliper will display on the image screen
Note: The three distances can be measured in dual image display format. First measurement can proceed in the midsagittal plane, and the second measurement can proceed in axial plane.
3. Proceed with the single and dual distance measurement.
4. The system will display distance and thyroid volume in the results window.

Add or remove measurement items in the measurement configuration menu based on their own requirements.

9.3.2 M mode measurements

In M mode, the measurement menu includes these measurement items:

- Depth
- Distance

Refer to the Generic measurement in detail for those measurements.

Add or remove measurement items in the measurement configuration menu based on their own requirements.

9.3.3 PW mode measurements

In PW mode, measurements include these measurement folders:

- Generic measurement folder
- Vessel measurement folder

Increase or reduce measurement items in the measurement setting menu based on their own requirement. Refer to "PW" mode measurement setting information in detail.

Generic measurement folder

In "PW" mode, the general measurement folder includes these measurement items:

- Velocity
- PS (systole peak speed)
- ED (diastole end speed)
- MD (Minimum speed in diastole period)
- TAMAX (maximum speed in time average)
- PI (Pulsatility index)
- RI (resistance index)
- PS/ED
- ED/PS
- A/B ratio
 - Velocity
 - Time
 - Acceleration
- FLOWVOL (flow volume)
- Max PG (Maximum pressure gradient)
- Mean PG (Mean pressure gradient)
- SV-D (Stroke Volume)
 - SV Diam (stroke volume diameter)
 - SVTAMAX (stroke volume maximum speed in time average)

Refer to the Generic measurement in detail for "PW" measurements.

Vessel measurement folder

In "PW" mode, the vessel measurement folder normally includes these items:

- Velocity
- PS (systole peak speed)
- ED (diastole end speed)
- MD (Minimum speed in diastole period)
- TAMAX (maximum speed in time average)
- PI (Pulsatility index)
- RI (resistance index)
- PS/ED
- ED/PS

Add or remove measurement items in the measurement configuration menu based on their own requirements

9.4 Carotid measurements

Brief introduction

Based on different applications, carotid measurement provides several different measurement items:

- Carotid artery
- Upper artery
- Upper vein
- Lower artery
- Lower vein
- Vessel puncture
- Trans-cranial Doppler

9.4.1 2D mode measurements

In the vascular application measurement menu includes generic measurement and specific measurements, such as vessel wall intima-media thickness etc.

In 2D mode, generic measurements in the carotid application include measurements as follows:

- Depth
- Distance
- Stenosis
- A and B ratio

In 2D mode, specific measurements in the vessel application include measurement items as follows:

IMT (intima-media thickness) measurement

Intima-media average thickness can be measured to be the index of arteriosclerosis.

Note: Due to the character of the ultrasound image principle, the rear wall IMT measurement is more accurate than antetheca.

Manual IMT measurement

The steps are as follows

1. Select "Manual" method for "Ant.CCA IMT" or "Post.CCA IMT" (carotid artery intima-media thickness) in measure config page.
2. Scan the carotid artery to gain relevant good image quality and press "Freeze".
3. Amplify the image in order to identify vessel intima, media, and extima.
4. Enter "Measure".
5. Select the proper direction (left or right and rear wall or antetheca) "CCA IMT".
6. Move caliper and trace extima inter-side of carotid artery. Fix the first caliper and the system display another operating caliper.
7. Move the caliper and trace intima inter-side of carotid artery.
8. Complete the measurement. The system will automatically calculate vessel wall intima-media average thickness for tracing part.

Auto IMT measurement

Auto IMT measurement means to measure the intima thickness of far field and near field vessel wall. Intima thickness of near field means the distance between extima and intima. Intima thickness of far field means the distance between extima and intima in far field.

The steps are as follows:

1. Select "Auto" method for "Ant.CCA IMT" or "Post.CCA IMT" (carotid artery intima-media thickness) in measure config page.
2. Scan carotid artery to gain relevant good image quality and press "Freeze".
3. Amplify the image in order to identify the vessel intima, media, and extima.
4. Enter "Measure".
5. Select the proper direction (left or right and rear wall or antetheca) CCA IMT.
6. Draw one rectangle, make sure that one section of the intima is inside the rectangle.
7. Complete the measurement. The system will display the measurement result about intima-media thickness as follows:
 - Average
 - Max
 - Min
 - Standard Deviation
 - Valid Points

CCA IMT

The steps are as follows:

1. Scan carotid artery to gain relevant good image quality and press "Freeze".
2. Amplify the image in order to identify the vessel intima, media, and extima.
3. Enter "Measure". Select "CCA IMT R" or "CCA IMT L".
4. Draw one rectangle, make sure that one section of the artery (both rear wall and antetheca are included) is inside the rectangle.
5. Complete the measurement. The system will display the measurement result about intima-media thickness as follows:
 - Average
 - Max
 - Min
 - Standard Deviation
 - Valid Points

Vas Plaque (Vascular sclerosis atheromatous plaque grade)

The steps are as follows:

1. Scan carotid artery to gain a good image quality and then press "Freeze".
2. Amplify the image in order to identify vessel intima, media, and extima.
3. Enter "Measure".
4. Select "Vas Plaque".
5. Input and select Vas Plaque measurement parameter:
 - Change the assigned area number and vascular wall limited thickness. Factory default setting is 3 and limited thickness is 1.0 cm
 - Select displayed measurement result parameter in configuration page:
 - Maximum value in each area
 - Average value in each area
 - Variance yield in each area
 - Maximum value in all measurements
 - Average value in all measurements
 - Variance yield in all measurements
6. After complete the setting, return to the measurement menu. The system will display a horizontal line and several vertical lines. The number of vertical lines is determined by assigned areas. The interval line divides the whole image area equally.
7. Adjust the horizontal line in order to be parallel with vascular wall. Complete the adjustment. The system will display another caliper.
8. Measure the thickness in any place as required.
9. The system displays the following measurement and calculation results:

- All measurement results
- Display all parameters which are set in setting menu
 - Maximum value in each area
 - Average value in each area
 - Variance yield in each area
 - Maximum value in all measurements
 - Average value in all measurements
 - Variance yield in all measurements

The number of all measurement points which exceed vascular wall limitation and the number of all areas which exceed vascular wall limitation.

9.4.2 M mode measurements

In M mode, measurement menu includes measurement items as follows:

- Depth
- Distance
- Stenosis
- A and B ratio
- Heart rate

Refer to the Generic measurement in detail for those measurements.

Add or remove measurement items in the measurement configuration menu based on their own requirements

9.4.3 PW mode measurements

In "PW" mode, measurement menu include measurement folders as follows:

- Generic measurement folder
- Arteria carotid communis measurement folder
- Internal carotid measurement folder
- External carotid measurement folder
- VA measurement folder
- BULB measurement folder
- BIF measurement folder
- STA measurement folder
- InnomA measurement folder
- Middle cerebral artery measurement folder
- Posterior cerebral artery measurement folder

Add or remove measurement items in the measurement configuration menu based on their own requirements

Generic measurement folder

In "PW" mode, the general measurement folder includes items as follows:

- Velocity
- Time
- Acceleration
- PS (systole peak speed)
- ED (diastole end speed)
- MD (Minimum speed in diastole period)
- TAMAX (maximum speed in time average)
- TAMEAN (mean speed in time average)PI (Pulsatility index)
- RI (resistance index)
- PS/ED
- ED/PS
- A/B ratio
 - Velocity
 - Time
 - Acceleration
- FLOWVOL (flow volume)
- HR

Other vascular measurement folder:

In "PW" mode, the vascular measurement folder includes measurement items as follows:

- Velocity
- Time
- Acceleration
- PS (systole peak speed)
- ED (diastole end speed)
- MD (Minimum speed in diastole period)
- TAMAX (maximum speed in time average)
- TAMEAN (mean speed in time average)
- PI (Pulsatility index)
- RI (resistance index)
- PS/ED
- ED/PS
- A/B ratio
 - Velocity
 - Time

- Acceleration
- FLOWVOL (flow volume)
- HR

Add or remove measurement items in the measurement configuration menu based on their own requirements.

Vessel automatically tracing and measurement

The vessel auto tracing and measurement function can automatically detect and identify the heart cycles. For artery flow, it can automatically identify the "PS" (peak speed in systole period), "MD" (minimum speed in diastole) and "ED" (end speed in diastole), and then automatically calculate the "PI" (pulsatility index) and "RI" (resistance index). For vein flow, it can automatically detect the peak velocity (PV).

Activate vessel auto tracing and measurement

The system supports auto tracing and measurement during live scanning, freeze and cine loop.

To activate auto tracing and measurement function, select the Live option in the "Auto Trace" menu of the touch panel in "PW" mode (automatically display auto tracing and measurement in real scanning image) or the "Frozen" option (automatically display auto tracing and measurement infrozen image). To stop vascular auto tracing and measurement, select "Off".

Set vascular auto tracing and measurement parameter

- Select vascular auto tracing method.
- Select maximum or average speed continuous trace.
- Select Max or Mean in "Trace Method" menu on the touch panel
- Select tracing direction.
- Tracing detection can be used in above baseline, below baseline or combination (above, below) peak velocity data. Select "Above", "Below" or "Both" in the "Trace Direction" menu in order to set peak velocity data.

Set vascular auto tracing and measurement result

After selecting the Dynamic or Static option in the "Auto trace" menu in "PW" mode, the operator can set which measurement and calculation results will be displayed in the vascular auto tracing and measurement result window. The following parameters can be selected: PS, MW, TAMAX, TAMEAN, TAMIN, PI, RI, PS/ED, ED/PS, PV and HR.

Note: PV is to detect peak velocity in vein flow. So it is mutually exclusive from other measurements. In other words, if PV is selected, other measurements will be isolated.

The following steps are to execute auto tracing and measurement

1. Reboot system.
2. Proceed with scanning.
3. Activate the auto vascular tracing and measurement function (Dynamic or Static).
The system will automatically execute tracing, measurement and calculation.
Note: Select in real time which measurement and calculation will be displayed in the auto vascular tracing and measurement result window through vascular auto tracing and measurement setting menu. Selectable parameters are PS, ED, MD, TAMAX, TAMEAN, TAMIN, PI, RI, PS/ED, ED/PS, PV and HR. PV is to detect peak velocity of vein flow. It is mutually exclusive of other measurements; that is, once PV is selected, other measurements are automatically isolated.
4. Press "Freeze", all vascular measurement and calculation results will display in the results window.

9.5 Gynecology Measurements

Introduction:

Gynecology measurements provide several types of measurement items:

- Uterus and Pelvis
- Follicle

9.5.1 2D Mode measurements

For Gynecology measurements, it includes general measurement items and some typical measurement items, such as Uterus Volume (Uterus), Ovary Volume(OV), Follicle Volume and Endometriosis Thickness(En.). For general measurements of 2D mode, it mainly includes "Depth" and "Distance" measurement items. Refer to chapter "General Measurements" in detail.

- Depth
- Distance

The typical measurement items of Gynecology application are as follows:

UT (Uterus Volume)

To calculate Uterus Volume, make three distance measurements. The steps are as follows:

1. Enter "Measure".
2. Select UT, and an active tracing caliper displays.
3. Perform a standard distance measurement. The system displays the distance value in the results window.
4. Repeat Step 3 to make the second and third distance measurement.

Note: Make three distance measurements in the dual display format by pressing the "Left" / "Right" on the control panel.

5. After the third distance measurement is completed, the system displays the uterus volume in the results window.

OV (Ovary Volume)

To calculate Ovary Volume, make three distance measurements as normal. The steps are as follows:

1. Enter "Measure".
2. Select OV(L) or OV(R), and an active tracing caliper displays.
3. Perform a standard distance measurement. The system displays the distance value in the results window.
4. Repeat Step 3 to make the second and third distance measurement.
Note: Three distance measurements can be made in the dual display format by pressing "Left" / "Right" on the control panel.
5. After the third distance measurement is completed, the system displays the ovary volume in the results window.

Follicle (Follicle Volume)

To measure Follicle Volume, the steps are as follows:

1. Enter "Measure".
2. Select "Follicle (L)" or "Follicle (R)".
3. Select the measurement method or use the default one and an active tracing caliper displays.
4. Perform a standard distance measurement. The system displays the distance value in the results window.
5. Repeat Step 3 to make the second and third distance measurement.
Notes:
Refer to chapter "General Measurements" for the single distance, dual distance and three distance measurement methods. As for "Mean" measurement method, three distance measurements are needed to calculate the follicle volume. Three distance measurements can be made in the dual display format by pressing "Left" / "Right" on the control panel.
6. After the third distance measurement is completed, the system displays the follicle volume in the results window.

Auto Follicle

Automatically measure follicular volume, the steps are as follows:

1. Enter "Measure".
2. Choose "Auto Follicle".
3. Choose left or right.
4. The system will automatically recognize the follicles, and automatically calculate the volume of follicles

En.(Endometriosis Thickness)

To measure Endometriosis Thickness, the steps are as follows:

1. Enter "Measure".
2. Select "En.", and an active tracing caliper displays on the image screen
3. Perform a standard distance measurement. The system displays the endometriosis thickness in the results window.

Tumor Uterus

To measure Tumor Uterus there are 6 methods: L, Ellipse, L&W, L&W&H, Ellipse&H, Trace&H.

Tumor Cervix

To measure Tumor Cervix there are 6 methods: L, Ellipse, L&W, L&W&H, Ellipse&H, Trace&H.

Cervix L, Cervix W, Cervix H

To measure Cervix L/W/H there are 4 methods: Distance, Polygon, Spline, Trace.

The measurement menu of Gynecology application can be configured by adding or removing the measurement items in 2D mode. Refer to "Measurement Menu Configuration" in the chapter

"General Measurements" for how to configure of the measurement menu.

9.5.2 PW mode measurements

In "PW" mode of Gynecology application, it includes measurement folders as follows:

- General Measurement Folder
- Ao (Aorta) Measurement Folder
- Desc. Aorta Measurement Folder
- Umbilical Measurement Folder
- Placenta Measurement Folder
- Uterus Measurement Folder

- Follicle Measurement Folder
- MCA Measurement Folder

Add or remove the measurement folders in "PW" mode, please refer to measurement configuration.

General Measurement Folder

In the General Measurement Folder, it includes measurement items as follows:

- Velocity
- PS
- EDMD
- TAMAX
- PI
- RI
- PS/ED
- ED/PS
- A/B Ratio
 - Velocity
 - Time
 - Acceleration
- HR

Other Measurement Folders

In the other Measurement Folders, they include the measurement items as follows. It might have minor differences depending on the different factory settings.

- Velocity
- PS
- ED
- MD
- TAMAX
- PI
- RIPS/ED
- ED/PS
- A/B Ratio
 - Velocity
 - Time
 - Acceleration
- HR

9.6 Urology Measurements

Introduction

Urology measurements provide several types of measurement items:

- Bladder
- Prostate
- Renal
- Kidney and ureter
- Pelvic Floor dysfunction

9.6.1 2D Mode measurements

Urology measurements include general measurement items and some typical measurement items, such as Bladder Volume, Renal Length, Renal Volume and Prostate Volume. General measurements in 2D mode include measurement items as follows. Refer to the chapter "General Measurements" in detail.

- Depth
- Distance
- Volume
- Angle
- Stenosis
- A/B Ratio

The typical measurement items of Urology application are as follows:

Bladder volume

There are 2 methods to measure bladder volume: Manual and Auto.

Manual method:

1. Press "Measure" key.
2. Select "Bladder Volume", and then a caliper will display on the image screen
Note: Three distances can be measured in the dual image display format. The first measurement can be processed in the midsagittal plane, and the second measurement can be processed in the axial plane. To use the dual image display format, press "Left" or "Right".
3. Proceed with the single and dual distance measurement.
4. The system will display three distances and the bladder volume result in the results window.

Auto method:

1. Press "Measure" key.
2. Select "Bladder Volume" measurement.

3. Select "Auto".
4. Touch on the image.
5. Unfreeze the system, change scanning section, enter measure again, and touch on the image.
6. The system will get the result of bladder volume automatically.

Renal Length

To measure Renal Length, the steps are as follows:

1. Enter "Measure".
2. Select "Renal Len.(L)" or "Renal Len.(R)", and an active tracing caliper displays.
3. Perform a standard distance measurement. The system displays the renal length in the results window.

Renal Volume

To calculate Renal Volume, make three distance measurements. The steps are as follows:

1. Enter "Measure".
2. Select "Renal Vol.(L)" or "Renal Vol.(R)", and an active tracing caliper displays.
3. Perform a standard distance measurement. The system displays the distance value in the results window.
4. Repeat Step 3 to make the second and third distance measurement.
Note: Three distance measurements can be made in the dual display format by pressing "Left" / "Right".
5. After the third distance measurement is completed, the system displays the renal volume in the results window.

Prostate Volume

To calculate Prostate Volume, make three distance measurements. The steps are as follows:

1. Enter "Measure".
2. Select "Prostate Vol.", and an active tracing caliper displays on the image screen
3. Perform a standard distance measurement. The system displays the distance value in the results window.
4. Repeat Step 3 to make the second and third distance measurement.
Note: Three distance measurements can be made in the dual display format by pressing "Left" / "Right".
5. After the third distance measurement is completed, the system displays the prostate volume in the results window.

PSAD and PPSA Measurement

"PSAD" and "PPSA" measurements can be made after Prostate Volume measurement. The definition of PSAD and PPSA is as follows.

PSAD : Prostatic Specific Antigen (PSA) Density – defined as: $PSAD = PSA/Volume$

PPSA : Predicted Prostate Specific Antigen – defined as: $PPSA = Volume \times PPSA \text{ Coefficient}$

To measure PSAD and PPSA, the steps are as follows:

1. Enter "Measure".
2. Measure "Prostate Volume".
3. Select "PSA" and "PPSA Coefficient", edit the coefficients.
4. Enter the value of "PSA" and "PPSA Coefficient" in the above coefficient window.
Note: The value of "PSA" and "PPSA Coefficient" can be entered at the urology patient screen also.
5. PSAD and PPSA are automatically calculated, and the system displays the value in the results window.

Pelvic Floor Dysfunction Measurement

BNR (Bladder Neck Rest) Measurement

To take the Bladder Neck Rest Measurement, the steps are as follows:

1. Acquire the bladder image when the patient is in the rest status and press "Freeze".
2. Enter "Measure".
3. Select "BNR", and a horizontal baseline displays on the image screen
4. Adjust the position of the baseline at the trailing edge of the symphysisosslum pubis, and fix it.
Note: It shows positive values below the baseline and negative values above the baseline.
5. When the baseline is fixed, an active tracing caliper displays on the image screen. Position the caliper at the leading edge of the bladder neck.
6. Perform a standard distance measurement, and the system displays the value in the results window.

BNS (Bladder Neck Stress) Measurement

To take the Bladder Neck Stress Measurement, the steps are as follows:

1. Acquire the bladder image after the patient finishes the "Valsalva" and touch "Freeze".
2. Enter "Measure".
3. Select "BNS", and a horizontal baseline displays on the image screen.

4. Adjust the position of the baseline at the trailing edge of the symphysisosslum pubis, and fix it. Note: It shows positive values below the baseline and negative values above the baseline.
5. When the baseline is fixed, an active tracing caliper displays. Put the caliper at the leading edge of the bladder neck.
6. Perform standard distance measurement, and the system displays the value in the results window.

BND (Bladder Neck Down) Measurement

To take the Bladder Neck Down Measurement. The steps are as follows:

1. Measure "BNR" and "BNS".
2. Select "BND", and the system displays the BND value in the results window.

Note: $BND = BNR - BNS$

DWT (Detrusor Wall Thickness) Measurement

To measure Detrusor Wall Thickness, make three distance measurements on the wall of the bladder. The steps are as follows:

1. Enter "Measure".
2. Select "DWT", and an active tracing caliper displays on the image screen
3. Perform a standard distance measurement. The system displays the distance value in the results window.
4. Repeat Step 3 to make the second and third distance measurement.
5. After the third distance measurement is completed, the system displays the average detrusor wall thickness in the results window.

RUV (Residual Urine) Measurement

To calculate Residual Urine, make two distance measurements. The steps are as follows:

1. Enter "Measure".
2. Select "RUV", and an active tracing caliper displays on the image screen
3. Perform a standard distance measurement. The system displays the distance value in the results window.
4. Repeat Step 3 to make the second distance measurement.
5. When the second distance measurement is completed, the system calculates the residual urine automatically and displays the value in the Results Window.

Note: $RUV(ml) = D1(cm) \times D2(cm) \times 5.9 - 14.9$.

UTDMAX (Maximum Uterine Down Position) Measurement

To measure the maximum position of uterine down, the steps are as follows:

1. Acquire the uterine image when the patient is on the stress status and touch "Freeze" button.
2. Enter "Measure".
3. Select "UTDMAX", and a horizontal baseline displays on the image screen
4. Adjust the position of the baseline at the trailing edge of the symphysisosslum pubis, and fix it.
Note: Positive values are shown below the baseline and negative values above the baseline.
5. When the baseline is fixed, an active tracing caliper displays. Put the caliper at the bottom position of the uterus.
6. Perform a standard distance measurement, and the system displays the value in the results window.

RADMAX (Maximum Ampulla Recti Down Position) Measurement

To measure the maximum position of ampulla recti down, the steps are as follows:

1. Acquire the image of ampulla recti when the patient is in the stress status and touch "Freeze".
2. Enter "Measure".
3. Select "RADMAX", and a horizontal baseline displays on the image screen.
4. Adjust the position of the baseline at the trailing edge of the symphysisosslum pubis, and fix it.
Note: Positive values are shown below the baseline and negative values above the baseline.
5. When the baseline is fixed, an active tracing caliper displays. Position the caliper at the bottom of the ampulla recti.
6. Perform a standard distance measurement, and the system displays the value in the results window.

Rectocele Depth and Width Measurement

To measure Rectocele Depth and Width, make two distance measurements. The steps are as follows:

1. Enter "Measure".
2. Select "Rectocele", and an active tracing caliper displays on the image screen
3. Perform one standard distance measurement, and the system displays the rectocele depth in the results window.

4. Perform another standard distance measurement, and the system displays the rectocele width in the results window.

Levator Hiatus Stress Measurement

To measure Levator Hiatus Stress, make two distance measurements and the system calculates the area automatically. The steps are as follows

1. Enter "Measure".
2. Select "Levator Hiatus Stress", and an active tracing caliper displays on the image screen
3. Perform the first standard distance measurement.
4. Perform the second standard distance measurement.
5. Calculate the area of levator hiatus automatically, and the system displays the values in the results window.

9.6.2 PW Mode measurements

The "PW" mode of Gynecology application includes General Measurement Folder.

The General Measurement Folder includes the following measurement items:

- Velocity
- PS
- ED
- MD
- TAMAX
- PI
- RI
- PS/ED
- ED/PS
- FLOW VOL

9.7 Pediatric Measurements

Introduction

Pediatric measurements provide several types of measurement items:

- Neonatal Head
- Neonatal Abdomen
- Pediatric Abdomen
- Pediatric Hip
- FAST

9.7.1 2D Mode measurements

Pediatric measurements include general measurement items and some typical measurement items, such as HIP(α), HIP($\alpha\beta$), and acetabular cartilage thickness. General measurements of 2D mode mainly consist of the following measurement items. Refer to the chapter "General Measurements" for more detailed information.

- Distance
- Area
- Volume
- Angle
- Stenosis
- A/B Ratio

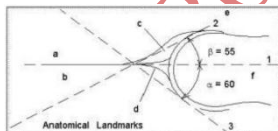
The typical measurement items of Pediatric application are as follows:

Pediatric Hip Dysplasia Measurement

It is helpful to evaluate children's hip dysplasia by calculating the HIP(α) and HIP($\alpha\beta$). To calculate

HIP(α) and HIP($\alpha\beta$), three lines are defined as follows:

1. Baseline, a line connected acetabular convexity and the cross point among the joint capsule, perichondrium and ilium.
2. Acetabular roof line (Line α), a line connected acetabular convexity and inferior to hip.
3. Inclination line (Line β), a line connected acetabular convexity and acetabular labrum. Angle α is the angle between baseline and line α , and angle β is the angle between baseline and line β .



| | | |
|---------------|-------|-----------------------|
| β line | a / b | : Ilium |
| | c | : Acetabular labrum |
| Baseline | d | : Many strands of top |
| α line | e | : Acetabular roof |
| | f | : Caput Femoris |

HIP(α)

To measure HIP(α). The steps are as follows:

1. Enter "Measure".
2. Select "HIP(α)(L)" or "HIP(α)(R)", and a horizontal line displays on the image screen.
3. Adjust the baseline to align with the acetabular convexity.
4. Adjust the inclination of the baseline.
5. Fix the baseline, and the system displays the line.
6. Adjust the inclination of the line α .

7. Fix the line α , and the system displays the angle α in the results window.

HIP($\alpha\beta$)

To measure HIP($\alpha\beta$). The steps are as follows:

1. Enter "Measure".
2. Select "HIP($\alpha\beta$)(L)" or "HIP($\alpha\beta$)(R)", and a horizontal line displays on the image screen
3. Adjust the baseline to align with the acetabular convexity.
4. Adjust the inclination of the baseline.
5. Fix the baseline, and the system displays the line α .
6. Adjust the inclination of the line α .
7. Fix the line α , and the system displays the line β .
8. Adjust the inclination of the line β .
9. Fix the line β , and the system displays the angle α and angle β in the results window.

Measurement configuration of HIP($\alpha\beta$)

The steps are as follows:

1. Select the configuration menu of "HIP($\alpha\beta$)" measurement, and the system shows its measurement method as shown below:
2. Select the measurement method "Group" or "Ungroup" to complete the measurement setting.

Note: Baseline, line α and line β always intersect at the acetabular convexity. Therefore, the operator should keep the three lines intersect at one point when using either the Group method or Ungroup method.

Pediatric Hip Dysplasia Classification on the HIP($\alpha\beta$) measurements

The steps are as follows:

1. Select "Hip Growth Type Definition" after the "HIP($\alpha\beta$)" measurements, and the system shows the pediatric hip dysplasia classification.
2. The pediatric hip dysplasia type can be rated based on the result of the HIP($\alpha\beta$) measurements.

Acetabular Cartilage Thickness

To measure Acetabular Cartilage Thickness, make a single distance measurement. The steps are as follows:

1. Enter "Measure".
2. Select "ACT", and an active tracing caliper displays on the image screen
3. Perform one standard distance measurement, and the system displays the acetabular cartilage thickness in the results window.

9.7.2 PW mode measurements

The "PW" mode of Pediatric application includes the following measurement folder:

- General Measurement Folder
- Anterior cerebral artery measurement folder
- Middle cerebral artery measurement folder
- Posterior cerebral artery measurement folder

General Measurement Folder

In the General Measurement Folder, it includes measurement items as follows:

- Velocity
- PS
- ED
- MD
- TAMAX
- PI
- RI
- PS/ED
- ED/PS
- Flow VOL

The measurement menu of Urology application can be configured by adding or removing the measurement items in "PW" mode. Refer to "Measurement Menu Configuration" in the chapter "General Measurements" for how to make the configuration of the measurement menu.

9.8 Obstetrics Measurements

Examination Preparation:

Prior to an ultrasound examination, the patient should be informed of the clinical indication, specific benefits, potential risks, and alternatives, if any. In addition, if the patient requests information about the exposure time and intensity, it should be provided. Patient access to educational materials regarding ultrasound is strongly encouraged to supplement the information communicated directly to the patient. Furthermore, these examinations should be conducted in a manner and take place in a setting which assures patient dignity and privacy.

- Prior material knowledge and approval of the presence of nonessential personnel with the number of such personnel kept to a minimum.
- An intent to share the information obtained with the parents per the physician's judgment, either during the examination or shortly thereafter.
- An offer of choice about viewing the fetus.
- An offer of choice about learning the sex of the fetus, if such information becomes available. However, an ultrasound examination should not be carried out for the sole purpose of identifying the sex of the fetus.

- Ultrasound examination performed solely to satisfy the family's desire to know the sex of the fetus, to view the fetus, or to obtain a picture of the fetus should be discouraged.

Acoustic Output Considerations

General warning

This device is a multi-use device which is capable of exceeding FDA pre-enactment acoustic output (spatial peak temporal average) intensity limits for fetal applications.

CAUTION

It is prudent to conduct an examination with the minimum amount and duration of acoustic output necessary to optimize the image's diagnostic value.

Concerns surrounding fetal exposure

Always be aware of the acoustic output level by observing the Acoustic Output Display. In addition, become thoroughly familiar with the Acoustic Output Display and equipment controls affecting output.

Training

It is recommended that all operators receive proper training in fetal Doppler applications before performing them in a clinical setting. Contact a local sales representative for training assistance please.

Introduction

Obstetrics measurements provide several types of measurement items:

- OB Early
- OB Mid/Late
- Fetal Heart

9.8.1 2D Mode measurements

Obstetrics measurements include general measurement items and some typical measurement items, such as GS, CRL, NT, OB Ratio, Estimated Fetal Weight, OB Curve and OB Table. General measurements of 2D mode mainly consist of the measurement items below. Refer to the chapter "General Measurements" for more detailed information.

- Depth
- Distance
- A/B Ratio

The typical measurement items of Obstetrics application are as shown below:

Gestational Sac (GS)

To measure the size of gestational sac, the method of measurement can be configured:

1. Enter "Measure".
2. Select "GS" with the measurement method "Max", and an active tracing caliper displays.

3. Perform a standard distance measurement, and the system displays the maximum diameter of the gestational sac in the results window.

To calculate the size of gestational sac with the "Mean" measurement method, make three distance measurements. The steps are as follows:

1. Enter "Measure".
2. Select "GS" with the measurement method "Mean", and an active tracing caliper displays on the image screen.
3. Perform a standard distance measurement. The system displays the distance value in the results window.
4. Repeat Step 3 to make the second and third distance measurement.
Note: Three distance measurements can be made in the dual display format by pressing "Left" / "Right".
5. After the third distance measurement is completed, the system displays the average diameter of the gestational sac in the results window.

Yolk Sac (YS)

To measure the size of Yolk Sac, the steps are as follows:

1. Enter "Measure".
2. Select "YS", and an active tracing caliper displays on the image screen.
3. Perform a standard distance measurement. The system displays the size of yolk sac in the results window.

Crown-rump Length (CRL)

To measure the Crown-rump Length, the steps are as follows:

1. Enter "Measure".
2. Select "CRL", and an active tracing caliper displays on the image screen.
3. Perform a standard distance measurement. The system displays the crown-rump length in the results window.

Nuchal Translucency Thickness

To measure the Nuchal Translucency Thickness, if select the method "Manual", the steps are as follows:

1. Enter "Measure".
2. Select "NT", and an active tracing caliper displays on the image screen.
3. Perform a standard distance measurement. The system displays the nuchal translucency thickness in the results window.

If select the method "Auto", the steps are as follows:

1. Enter "Measure".
2. Select "NT", and an active tracing caliper displays on the image screen.
3. Fix one dotted box in the interest area, the system will provide the measurement value automatically.

Uterus Volume (UT)

To calculate Uterus Volume, make three distance measurements. The steps are as follows:

1. Enter "Measure".
2. Select "UT", and an active tracing caliper displays on the image screen.
3. Perform a standard distance measurement. The system displays the distance value in the results window.
4. Repeat Step 3 to make the second and third distance measurement.
Note: Three distance measurements can be made in the dual display format by pressing "Left" / "Right".
After the third distance measurement is completed, the system displays the uterus volume in the results window.

Endometriosis Thickness (En.)

To measure Endometriosis Thickness, the steps are as follows:

1. Enter "Measure".
2. Select "En.", and an active tracing caliper displays on the image screen.
3. Perform a standard distance measurement. The system displays the endometriosis thickness in the results window.

Ovary Volume (OV)

To calculate Ovary Volume, make three distance measurements normally. The steps are as follows:

1. Enter "Measure".
2. Select "OV (L)" or "OV(R)", and an active tracing caliper displays on the image screen.
3. Perform a standard distance measurement. The system displays the distance value in the results window.
4. Repeat Step 3 to make the second and third distance measurement.
Note: Three distance measurements can be made in the dual display format by pressing "Left" / "Right".
5. After the third distance measurement is completed, the system displays the ovary volume in the results window.

Biparietal Diameter (BPD)

There are 2 methods: Manual and Auto.

To measure Biparietal Diameter with "Manual", the steps are as follows:

1. Enter "Measure".
2. Select "BPD", and an active tracing caliper displays on the image screen.
3. Perform a standard distance measurement. The system displays the biparietal diameter in the results window.

To measure Biparietal Diameter with "Auto", the steps are as follows:

1. Enter "Measure".
2. Select "BPD" measurement.

3. Select "Auto".
4. Touch on the image.
5. The system will get the result of BPD automatically.

Occipito-frontal Diameter (OFD)

There are 2 methods: Manual and Auto.

To measure Occipito-frontal Diameter, the steps are as follows:

1. Enter "Measure".
2. Select "OFD", and an active tracing caliper displays on the image screen.
3. Perform a standard distance measurement. The system displays the occipito-frontal diameter in the results window.

To measure **Occipito-frontal Diameter** with "Auto", the steps are as follows:

1. Enter "Measure".
2. Select "OFD" measurement.
3. Select "Auto".
4. Touch on the image.
5. The system will get the result of OFD automatically.

Head Circumference (HC)

To calculate Head Circumference, there are six measurement methods: BPD&OFD, Ellipse, Polygon, Spine and Trace. Ellipse and BPD&OFD method are the most common settings.

To measure Head Circumference with the "BPD&OFD" method, make two distance measurements. The steps are as follows:

1. Enter "Measure".
2. Select "HC".
3. Select the measurement method "BPD&OFD" as the default setting from the configuration menu, and an active tracing caliper displays on the image screen.
4. Perform a standard distance measurement. The system displays the distance value in the results window.
5. Repeat Step 3 to make the second distance measurement.
6. After the second distance measurement is completed, the system displays the head circumference in the results window.

To measure Head Circumference with the "Ellipse" method, make an ellipse measurement. The steps are as follows:

1. Enter "Measure".
2. Select "HC".
3. Select the measurement method "Ellipse", and an active ellipse displays on the image screen.
4. Position the active caliper of the ellipse.
5. Fix the start point. The system fixes the first caliper and displays a second active caliper.

6. Move the second caliper.
7. Adjust the "Ellipse" control and an ellipse with an initial circle shape displays.
7. Complete the measurement. The system displays the head circumference in the results window.

To measure Head Circumference with the "Polygon" method, make a polygon trace measurement. The steps are as follows:

1. Enter "Measure".
2. Select "HC".
3. Select the measurement method "Polygon", and an active tracing caliper displays on the image screen.
4. Move the caliper to the target position.
5. Fix the start point. The system fixes the first caliper and displays a second active caliper.
6. Move the second caliper.
7. The system fixes the second caliper and displays a third active caliper.
8. Move the third caliper.
9. The system fixes the third caliper and displays a next active caliper. Note: At least three calipers are needed to form a polygon.
10. Repeat Steps 8-9 to add more caliper of the polygon.
11. Complete the measurement. The system displays the head circumference in the results window. Note: The line can be erased little by little.

To measure Head Circumference with the "Spline" method, make a spline trace measurement. The steps are as follows:

1. Enter "Measure".
2. Select "HC".
3. Select the measurement method "Spline" as the default setting from the configuration menu, and an active tracing caliper displays on the image screen.
4. Move the active caliper to the target position.
5. Fix the start point. The system fixes the first caliper and displays a second active caliper.
6. Move the second caliper.
7. The system fixes the second caliper and displays a third active caliper.
8. Move the third caliper.
9. The system fixes the third caliper and displays a next active caliper. Note: At least three calipers are needed to form a spline.
10. Repeat Steps 8-9 to add more calipers to the spline.
11. Complete the measurement. The system displays the head circumference in the results window. Note: The line can be erased little by little.

To measure Head Circumference with the "Trace" method, the steps are as follows:

1. Enter "Measure".

2. Select "HC".
3. Select the measurement method "Trace" as the default setting from the configuration menu, and an active tracing caliper displays on the image screen
4. Move the active caliper to the target position.
5. The system fixes the first caliper and the trace caliper changes to an active tracing caliper.
6. To trace the measurement area, move the caliper around the anatomy.
7. Complete the measurement. The system displays the head circumference in the results window. Note: The line can be erased little by little.

Measure "HC" with "Auto" method:

1. Enter "Measure".
2. Select "HC" measurement.
3. Touch "Auto".
4. Touch the image.
5. The system will get the result of "HC" automatically.

Cerebellar Diameter (CD)

To measure Cerebellar Diameter, the steps are as follows:

1. Enter "Measure".
2. Select "CD", and an active tracing caliper displays on the image screen
3. Perform a standard distance measurement. The system displays the cerebellar diameter in the results window.

Transverse Cerebellar Diameter (TCD)

To measure Transverse Cerebellar Diameter, the steps are as follows:

1. Enter "Measure".
2. Select "TCD", and an active tracing caliper displays on the image screen
3. Perform a standard distance measurement. The system displays the transverse cerebellar diameter in the results window.

Binocular Diameter (BD)

To measure Binocular Diameter, the steps are as follows:

1. Enter "Measure".
2. Select "BD", and an active tracing caliper displays on the image screen
3. Perform a standard distance measurement. The system displays the binocular diameter in the results window.

Outer Orbital Diameter (OOD)

To measure Outer Orbital Diameter, the steps are as follows:

1. Enter "Measure".
2. Select "OOD", and an active tracing caliper displays on the image screen

3. Perform a standard distance measurement. The system displays the outer orbital diameter in the results window.

Inter Orbital Diameter (IOD)

To measure Inter Orbital Diameter, the steps are as follows:

1. Enter "Measure".
2. Select "IOD", and an active tracing caliper displays on the image screen
3. Perform a standard distance measurement. The system displays the inter-orbital diameter in the results window.

Humerus Length (HL)

To measure Humerus Length, the steps are as follows:

1. Enter "Measure".
2. Select "HL", and an active tracing caliper displays on the image screen
3. Perform a standard distance measurement. The system displays the humerus length in the results window.

Anter-posterior Abdominal Diameter (APAD)

To measure Anter-posterior Abdominal Diameter, the steps are as follows:

1. Enter "Measure".
2. Select "APAD", and an active tracing caliper displays on the image screen
3. Perform a standard distance measurement. The system displays the anter-posterior abdominal diameter in the results window.

Transverse Abdominal Diameter (TAD)

To measure Transverse Abdominal Diameter, the steps are as follows:

1. Enter "Measure".
2. Select "TAD", and an active tracing caliper displays on the image screen
3. Perform a standard distance measurement. The system displays the transverse abdominal diameter in the results window.

Abdominal Circumference (AC)

To calculate Abdominal Circumference, there are six measurement methods: APAD&TAD, Ellipse, Polygon, Spine and Trace. Ellipse and APAD&TAD method are the default settings.

To measure Abdominal Circumference with the "APAD&TAD" method, make two distance measurements. The steps are as follows:

1. Enter "Measure".
2. Select "AC".
3. Select the measurement method "APAD&TAD" as the default setting from the configuration menu, and an active tracing caliper displays on the image screen
4. Perform a standard distance measurement. The system displays the distance value in the results window.
5. Repeat Step 3 to make the second distance measurement.

6. After the second distance measurement is completed, the system displays the abdominal circumference in the results window.

To measure Abdominal Circumference with the "Ellipse" method, make an ellipse measurement. The steps are as follows:

1. Enter "Measure".
2. Select "AC".
3. Select the measurement method "Ellipse" as the default setting from the configuration menu, and an active ellipse displays on the image screen.
4. Move the active caliper of the ellipse.
5. Fix the start point. The system fixes the first caliper and displays a second active caliper.
6. Move the second caliper.
7. Adjust the "Ellipse" control and an ellipse with an initial circle shape displays.
8. Complete the measurement. The system displays the abdominal circumference in the results window.

To measure Abdominal Circumference with the "Polygon" method, make a polygon trace measurement. The steps are as follows:

1. Enter "Measure".
 2. Select "AC".
 3. Select the measurement method "Polygon" as the default setting from the configuration menu, and an active tracing caliper displays on the image screen.
 4. Move the caliper to the target position.
 5. Fix the start point. The system fixes the first caliper and displays a second active caliper.
 6. Move the second caliper.
 7. The system fixes the second caliper and displays a third active caliper.
 8. Move the third caliper.
 9. The system fixes the third caliper and displays a next active caliper. Note: At least three calipers are needed to form a polygon.
 10. Repeat Steps 8-9 to add more calipers to the polygon.
 11. Complete the measurement. The system displays the abdominal circumference in the results window.
- Note: The line can be erased little by little.

To measure Abdominal Circumference with the "Spline" method, make a spline trace measurement. The steps are as follows:

1. Enter "Measure".
2. Select "AC".
3. Select the measurement method "Spline" as the default setting from the configuration menu, and an active tracing caliper displays on the image screen.
4. Move the active caliper to the target position.

5. The system fixes the first caliper and displays a second active caliper.
6. Move the second caliper.
7. The system fixes the second caliper and displays a third active caliper.
8. Move the third caliper.
9. The system fixes the third caliper and displays a next active caliper. Note: At least three calipers are needed to form a spline.
10. Repeat Steps 8-9 to add more caliper of the spline.
11. Complete the measurement. The system displays the abdominal circumference in the results window.
Note: The line can be erased little by little.

To measure Abdominal Circumference with the "Trace" method, the steps are as follows:

1. Enter "Measure".
2. Select "AC".
3. Select the measurement method "Trace", and an active tracing caliper displays on the image screen
4. Move the active caliper to the target position.
5. The system fixes the first caliper and the trace caliper changes to an active tracing caliper.
6. To trace the measurement area, move the caliper around the anatomy.
7. Complete the measurement. The system displays the abdominal circumference in the results window.
Note: The line can be erased little by little.

Measure "AC" with "Auto" method:

1. Enter "Measure".
2. Select "AC" measurement.
3. Select "Auto".
4. Touch on the image.
5. The system will get the result of "AC" automatically.

Anter-posterior Trunk Diameter (APTD)

To measure Anter-posterior Trunk Diameter, the steps are as follows:

1. Enter "Measure".
2. Select APTD, and an active tracing caliper displays on the image screen
3. Perform a standard distance measurement. The system displays the anter-posterior trunk diameter in the results window.

Transverse Trunk Diameter (TTD)

To measure Transverse Trunk Diameter:

1. Enter "Measure".
2. Select "TTD", and an active tracing caliper displays on the image screen

3. Perform a standard distance measurement. The system displays the transverse trunk diameter in the results window.

Trunk Cross-sectional Area (AxT)

To calculate Trunk Cross-sectional Area, there are five measurement methods: APAD&TAD, Ellipse, Polygon, Spine and Trace. Ellipse and APTD&TTD method are the most common settings.

To measure Trunk Cross-sectional Area with the "APTD&TTD" method, make two distance measurements.

1. Enter "Measure".
2. Select "AxT".
3. Select the measurement method "APTD&TTD" as the default setting from the configuration menu, and an active tracing caliper displays on the image screen
4. Perform a standard distance measurement. The system displays the distance value in the results window.
5. Repeat Step 3 to make the second distance measurement.
6. After the second distance measurement is completed, the system displays the trunk cross-sectional area in the results window.

To measure Trunk Cross-sectional Area with the Ellipse method, make an ellipse measurement. The steps are as follows:

1. Enter "Measure".
2. Select "AxT".
3. Select the measurement method "Ellipse" as the default setting from the configuration menu, and an active ellipse displays on the image screen
4. To position the active caliper of the ellipse.
5. Fix the start point. The system fixes the first caliper and displays a second active caliper.
6. Move the second caliper.
7. Adjust the "Ellipse" control and an ellipse with an initial circle shape displays.
Note: To position the ellipse and to size the measured axes (move the calipers). Complete the measurement. The system displays the trunk cross-sectional area in the results window.

To measure Trunk Cross-sectional Area with the "Polygon" method, make a polygon trace measurement. The steps are as follows:

1. Enter "Measure".
2. Select "AxT".
3. Select the measurement method "Polygon" as the default setting from the configuration menu, and an active tracing caliper displays on the image screen
4. Move the caliper to the target position.
5. The system fixes the first caliper and displays a second active caliper.
6. Move the second caliper.

7. The system fixes the second caliper and displays a third active caliper.
8. Move the third caliper.
9. The system fixes the third caliper and displays a next active caliper.
Note: At least three calipers are needed to form a polygon.
10. Repeat Steps 8-9 to add more calipers to the polygon.
11. Complete the measurement. The system displays the trunk cross-sectional area in the results window.
Note: The line can be erased little by little.

To measure Trunk Cross-sectional Area with the "Spline" method, make a spline trace measurement. The steps are as follows:

1. Enter "Measure".
2. Select "AxT".
3. Select the measurement method "Spline", and an active tracing caliper displays on the image screen
4. Move the active caliper to the target position.
5. The system fixes the first caliper and displays a second active caliper.
6. Move the second caliper.
7. The system fixes the second caliper and displays a third active caliper.
8. Move the third caliper.
9. The system fixes the third caliper and displays a next active caliper.
Note: At least three calipers are needed to form a spline.
10. Repeat Steps 8-9 to add more caliper of the spline.
11. Complete the measurement. The system displays the trunk cross-sectional area in the results window.
12. Note: The line can be erased little by little.

To measure Trunk Cross-sectional Area with the "Trace" method, the steps are as follows:

1. Enter "Measure".
2. Select "AxT".
3. Select the measurement method Trace as the default setting from the configuration menu, and an active tracing caliper displays on the image screen
4. Move the active caliper to the target position.
5. The system fixes the first caliper and the trace caliper changes to an active tracing caliper.
6. To trace the measurement area, move the caliper around the anatomy.
7. Complete the measurement. The system displays the trunk cross-sectional area in the results window.
Note: The line can be erased little by little.

Fetal Trunk Area (FTA)

To calculate Fetal Trunk Area, there are five measurement methods: LTD&TTD, Ellipse, Polygon, Spline and Trace. Ellipse and LTD&TTD method are the most default settings.

To measure Fetal Trunk Area with the LTD&TTD method, make two distance measurements. The steps are as follows:

1. Enter "Measure".
2. Select "FTA".
3. Select the measurement method "LTD&TTD" as the default setting from the configuration menu and an active tracing caliper displays on the image screen
4. Perform a standard distance measurement. The system displays the distance value in the results window.
5. Repeat Step 3 to make the second distance measurement.
6. After the second distance measurement is completed, the system displays the fetal trunk area in the results window.

To measure Fetal Trunk Area with the Ellipse method, make an ellipse measurement. The steps are as follows:

1. Enter "Measure".
2. Select "FTA".
3. Select the measurement method "Ellipse" as the default setting from the configuration menu, and an active ellipse displays.
4. To position the active caliper of the ellipse.
5. Fix the start point. The system fixes the first caliper and displays a second active caliper.
6. Move the second caliper.
7. Adjust the "Ellipse" control and an ellipse with an initial circle shape displays.
Note: To position the ellipse and to size the measured axes (move the calipers).
8. Complete the measurement. The system displays the fetal trunk area in the results window.

To measure Fetal Trunk Area with the "Polygon" method, make a polygon trace measurement. The steps are as follows:

1. Press "Measure".
2. Select "FTA".
3. Select the measurement method "Polygon" as the default setting from the configuration menu, and an active tracing caliper displays on the image screen
4. Move the caliper to the target position.
5. The system fixes the first caliper and displays a second active caliper.
6. Move the second caliper.
7. The system fixes the second caliper and displays a third active caliper.
8. Move the third caliper.
9. The system fixes the third caliper and displays a next active caliper.
Note: At least three calipers are needed to form a polygon.
10. Repeat Steps 8-9 to add more caliper of the polygon.
11. Complete the measurement. The system displays the fetal trunk area in the results window. Note: The line can be erased little by little.

To measure Fetal Trunk Area with the "Spline" method, make a spline trace measurement. The steps are as follows:

1. Enter "Measure".
2. Select "FTA".
3. Select the measurement method "Spline" as the default setting from the configuration menu, and an active tracing caliper displays on the image screen
4. Move the active caliper to the target position.
5. Fix the start point. The system fixes the first caliper and displays a second active caliper.
6. Move the second caliper.
7. The system fixes the second caliper and displays a third active caliper.
8. Move the third caliper.
9. The system fixes the third caliper and displays a next active caliper.
Note: At least three calipers are needed to form a spline.
10. Repeat Steps 8-9 to add more caliper of the spline.
11. Complete the measurement. The system displays the fetal trunk area in the results window.
Note: The line can be erased little by little.

To measure Fetal Trunk Area with the "Trace" method, the steps are as follows:

1. Enter "Measure".
2. Select "FTA".
3. Select the measurement method "Trace" as the default setting from the configuration menu, and an active tracing caliper displays on the image screen
4. Move the active caliper to the target position.
5. The system fixes the first caliper and the trace caliper changes to an active tracing caliper.
6. To trace the measurement area, move the caliper around the anatomy.
7. Complete the measurement. The system displays the fetal trunk area in the results window.
Note: The line can be erased little by little.

Transverse Thorax Diameter (THD)

To measure Transverse Thorax Diameter, the steps are as follows:

1. Enter "Measure".
2. Select "THD", and an active tracing caliper displays on the image screen
3. Perform a standard distance measurement. The system displays the transverse thorax diameter in the results window.

Thorax Circumference (ThC)

To calculate Thorax Circumference, there are five measurement methods: L&W, Ellipse, Polygon, Spline and Trace. Ellipse and L&W method are the most default settings.

To measure Thorax Circumference with the L&W method, make two distance measurements. The steps are as follows:

1. Enter "Measure".
2. Select "THC".
3. Select the measurement method "L&W" as the default setting from the configuration menu, and an active tracing caliper displays on the image screen
4. Perform a standard distance measurement. The system displays the distance value in the results window.
5. Repeat Step 3 to make the second distance measurement.
6. After the second distance measurement is completed, the system displays the thorax circumference in the results window.

To measure Thorax Circumference with the Ellipse method, make an ellipse measurement. The steps are as follows:

1. Enter "Measure".
2. Select "THC".
3. Select the measurement method "Ellipse" as the default setting from the configuration menu, and an active ellipse displays on the image screen
4. To position the active caliper of the ellipse.
5. Fix the start point. The system fixes the first caliper and displays a second active caliper.
6. Move the second caliper.
7. Adjust the "Ellipse" control and an ellipse with an initial circle shape displays.
8. Complete the measurement. The system displays the thorax circumference in the results window.

To measure Thorax Circumference with the Polygon method, make a polygon trace measurement. The steps are as follows:

1. Enter "Measure".
2. Select "THC".
3. Select the measurement method Polygon as the default setting from the configuration menu, and an active tracing caliper displays.
4. Move the caliper to the target position.
5. Fix the start point. The system fixes the first caliper and displays a second active caliper.
6. Move the second caliper.
7. The system fixes the second caliper and displays a third active caliper.
8. Move the third caliper.
9. The system fixes the third caliper and displays a next active caliper.
Note: At least three calipers are needed to form a polygon.
10. Repeat Steps 8-9 to add more calipers to the polygon.
11. Complete the measurement. The system displays the thorax circumference in the Results Window. Note: The line can be erased little by little.

To measure Thorax Circumference with the Spline method, make a spline trace measurement. The steps are as follows:

1. Enter "Measure".
2. Select "THC".
3. Select the measurement method Spline as the default setting from the configuration menu, and an active tracing caliper displays.
4. Move the active caliper to the target position.
5. The system fixes the first caliper and displays a second active caliper.
6. Move the second caliper.
7. The system fixes the second caliper and displays a third active caliper.
8. Move the third caliper.
9. The system fixes the third caliper and displays a next active caliper.
Note: At least three calipers are needed to form a spline.
10. Repeat Steps 8-9 to add more caliper of the spline.
11. Complete the measurement. The system displays the thorax circumference in the results window.
Note: The line can be erased little by little.

To measure Thorax Circumference with the Trace method, the steps are as follows:

1. Enter "Measure".
2. Select "THC".
3. Select the measurement method Trace as the default setting from the configuration menu, and an active tracing caliper displays.
4. Move the active caliper to the target position.
5. The system fixes the first caliper and the trace caliper changes to an active tracing caliper.
6. To trace the measurement area, move the caliper around the anatomy.\
7. Complete the measurement. The system displays the thorax circumference in the results window.
Note: The line can be erased little by little.

Fetal Cardiac Thorax Diameter Ratio (CTDR)

To measure Fetal Cardiac Thorax Diameter Ratio, make two distance measurements. The steps are as follows:

1. Enter "Measure".
2. Select "CTDR", and an active tracing caliper display.
3. Perform a standard distance measurement. The system displays the distance value in the results window.
4. Repeat Step 3 to make the second distance measurement.
5. After the second distance measurement is completed, the system displays the cardiac thorax diameter ratio in the results window.

Fetal Cardiac Thorax Area Ratio (CTAR)

To measure Fetal Cardiac Thorax Area Ratio, make two area measurements. The steps are as follows:

1. Enter "Measure".
2. Select "CTAR", and an active tracing caliper displays.
3. Perform a standard area measurement with the default measurement method. The system displays the area value in the results window.
4. Repeat Step 3 to make the second area measurement.
5. After the second area measurement is completed, the system displays the cardiac thorax area ratio in the results window.

Spinal Length (SL)

To measure Spinal Length, the steps are as follows:

1. Enter "Measure".
2. Select "SL", and an active tracing caliper displays.
3. Perform a standard distance measurement. The system displays the spinal length in the results window.

Femur Length (FL)

To measure Femur Length, the steps are as follows:

1. Enter "Measure".
2. Select "FL", and an active tracing caliper displays.
3. Perform a standard distance measurement. The system displays the femur length in the results window.

Measure "FL" with "Auto" method:

1. Enter "Measure".
2. Select "FL" measurement.
3. Select "Auto".
4. Touch on the image.
5. The system will get the result of "FL" automatically.

Ulnar Length (ULNA)

To measure Ulnar Length, the steps are as follows:

1. Enter "Measure".
2. Select "ULNA", and an active tracing caliper displays.
3. Perform a standard distance measurement. The system displays the ulnar length in the results window.

Radius Length (RAD)

To measure Radius Length, the steps are as follows:

1. Enter "Measure".
2. Select "RAD", and an active tracing caliper displays.

3. Perform a standard distance measurement. The system displays the radius length in the results window.

Tibial Length (TIB)

To measure Tibial Length, the steps are as follows:

1. Enter "Measure".
2. Select "TIB", and an active tracing caliper displays.
3. Perform a standard distance measurement. The system displays the tibial length in the results window.

Fibular Length (FIB)

To measure Fibular Length, the steps are as follows:

1. Enter "Measure".
2. Select "FIB", and an active tracing caliper displays.
3. Perform a standard distance measurement. The system displays the fibular length in the results window.

Foot Length (Ft)

To measure Foot Length, the steps are as follows:

1. Enter "Measure".
2. Select "Ft", and an active tracing caliper displays.
3. Perform a standard distance measurement. The system displays the foot length in the results window.

Placenta Thickness (PT)

To measure Placenta Thickness, the steps are as follows:

1. Enter "Measure".
2. Select "PT", and an active tracing caliper displays.
3. Perform a standard distance measurement. The system displays the placenta thickness in the results window.

Amniotic Fluid Index (AFI)

To calculate the Amniotic Fluid Index, make measurements of the four quadrants of the uterine cavity. The system adds these four measurements together to calculate the Amniotic Fluid Index. The steps are as follows:

1. Enter "Measure".
2. Select "AFI". The first distance measurement, AFI-Q1, is already selected.
3. Make a standard distance measurement for the first quadrant:
 - a. To position the active caliper at the start point.
 - b. Fix the start point. The system fixes the first caliper and displays a second active caliper.
 - c. To position the second active caliper at the end point. A dotted line connects the measurement points.

- d. Complete the measurement. The system displays the distance value in the results window.
4. When the measurement of the first quadrant is completed, unfreeze the image and move to the second quadrant.
5. After the image is obtained, then "Freeze" and "Measure" are pressed. The system prompts to continue with the AFI measurements. Make sure that the next quadrant has been selected.
6. Perform a standard distance measurement for the second, third and fourth Quadrants, repeat step 2.
7. When all four quadrants have been measured, the system calculates the AFI total and displays it in the results window.

Cervix L, Cervix W, Cervix H

To measure Cervix L/W/H there are 4 methods: Distance, Polygon, Spline, Trace.

Nasal Bone

To measure Nasal Bone, the steps are as follows:

1. Enter "Measure".
2. Select "Nasal Bone", and an active tracing caliper displays.
3. Perform a standard distance measurement. The system displays the length of nasal bone in the results window.

Lat Ventricle

To measure Lat Ventricle, the steps are as follows:

1. Enter "Measure".
2. Select "Lat Ventricle", and an active tracing caliper displays.
3. Perform a standard distance measurement. The system displays the length of lat ventricle in the results window.

Internal os

To measure Internal os, the steps are as follows:

1. Enter "Measure".
2. Select "Internal os", and an active tracing caliper displays.
3. Perform a standard distance measurement. The system displays the length of internal os in the results window.

Cardiac Axis

To measure Cardiac Axis, the steps are as follows:

1. Enter "Measure".
2. Select "Cardiac Axis", and an active tracing caliper displays.
3. Perform a standard distance measurement. The system displays the length of cardiac axis in the results window.

OB Ratio:

- HC/AC
- FL/AC
- FL/BPD
- CI (BPD/OFD)
- FL/HC
- TCD/AC

To get the ratio result need to finish the two sub-items.

GA(LMP)

GA(LMP): Gestational age that is calculated based on the date of Last Menstrual Period.

GA(GA)

GA(GA): Gestational age(GA) is to show from the zona-binding count that day to birth. The normal maturity is 38 weeks (266 days) for the fetus. Because of zona-binding the time cannot be precisely calculated. It can only be estimated, and the average time could be reduced by 2 weeks according to the menstrual age calculation. When in the patient information, input the date of the last menstruation, and the system will automatically calculate the gestational age GA. Another method is to measure the results calculated according to some gestational age.

EDDbyLMP

EDDbyLMP: Estimated delivery date that is calculated from the time of Last Menstrual Period. When in the patient information, input the end time period of time, the system will automatically calculate the estimated delivery date by LMP (EDDbyLMP).

EDDbyGA

EDDbyGA: When the system obtains the gestational age(GA), the system will automatically calculate the delivery date gestational age estimates (EDDbyGA).

Multiple Fetus Measurement

The system allows to measure and report multiple fetus development. If more than one fetus is imaged during the examination, enter the number of fetuses in the patient information window, and there will be "ABCD" in measurement menu (take 4 fetuses for example):

- A, B, C, D is the specific fetus, and 4 is the fetal quantity.
- Switch among A/4, B/4, C/4 and D/4 to take the measurement on the specific fetus.

Estimated Fetal Weight (EFW)

Estimated Fetal Weight measurement is applied for OB Mid and OB Late application only. If "Auto Select EFW Method" is enabled in system setting, after do one or more OB related measurements, like BPD, FL, HC, AC, the system will select one method to calculate EFW automatically.

If it is disabled, select one method, then do the related measurements, the system will calculate EFW.

EFW methods are depended on the selected EFW table in the system setting.

OB Curve Graph

OB Graphs allow to assess fetal growth compared to a normal growth curve. When a patient has completed two or more ultrasound examinations, the graphs can be used to look at fetal trending. For multi-gestational patients can plot all fetuses and compare the growth on the graphs.

The system provides the following two basic types of graphs:

- **Fetal Growth Curve Graph** – show one measurement per graph. These graphs show the normal growth curve, positive and negative standard deviations or applicable percentiles, and ultrasound age of the fetus using the current measurement. For multi-gestational pregnancies can view all fetuses. If previous examination data is available, the graph can show fetal trending.
- **Fetal Growth Bar Graph** – shows the ultrasound age and the gestational age based on patient data. Plot all measurements on one graph.

To view OB graphs. The steps are as follows:

1. Enter "Measure".
2. Select "OB Graph" (only for OB application), select "Graph Type".
3. The system provides 5 types of display format on Fetal Growth Curve Graph: Single, Dual, Quad, Multi-fetal Compare and Multi-Fetal Parallel (these 2 types only work when there are 2 or more fetuses).
 - 3.1 Single display format displays a fetal growth curve graph of any a maternity measuring parameter. Dual display format displays two fetal growth curve graphs of any two maternity measuring parameters parallel. Quad display format displays four fetal growth curve graphs of any four maternity measuring parameters together.
 - 3.2 Multi-fetal Compare and Multi-Fetal Parallel are for the fetal growth curve graph of multiple fetuses. Multi-Fetal Compare displays the fetal growth curve graph of the comparison among all fetuses. Multi-fetal Parallel displays the fetal growth curve graphs of all fetus parallel in the separate graph.
4. The system provides two types of display format on Fetal Growth Bar Graph: Single and Multi- Fetal Parallel (only work when there are 2 or more fetuses).
 - 4.1 Single display format displays a fetal growth bar graph.
 - 4.2 Multi-fetal Parallel displays the fetal growth curve graphs of all fetus parallel in the separate graph.

Fetal Growth Curve Graph

- The horizontal axis shows the fetal age in weeks. The system determines this age from the data on the patient information window.
- The vertical axis shows one of the following:
 - For measurements, mm or cm

- For ratios, percent
- For fetal weight, grams
- The Fetal Growth Curve Graph shows the information for the selected measurement as follows:
 - The normal growth curve
 - The standard deviations or relevant percentiles
 - The gestational age of the fetus, using patient data (vertical dotted line)
 - Using the current ultrasound measurement data, where the fetus is on the growth curve
- The legend at the bottom of the graph shows the symbols and colors that indicate data for fetal trending (Past and Present), and multiple gestation (Fetus) in the Multi-Fetal Compare Display format.
- To select which measurement want to display on the Fetal Growth Curve Graph:
 - a. On the graph display, the system displays a list of measurements.
 - b. Select the desired measurement. The system displays the Fetal Growth Curve Graph for the selected measurement.

Fetal Growth Bar Graph

- The fetal growth bar graph shows current examination measurements and the normal growth range based on the gestational age. It shows all measurements on one graph.
 - The horizontal axis shows the gestational weeks.
 - The red vertical shows GA by LMP or EDD.
 - The white "X" shows the ultrasound average age using the current measurement.
 - The green rectangle shows the normal age range for the measurement.
- To add a new measurement to be displayed on the Fetal Growth Bar Graph, do one of the following:
 - a. On the graph display, the system displays a list of measurements.
 - b. Select the desired measurement. The system displays the new selected measurement on the Fetal Growth Bar Graph.

To Edit Patient Data on the Fetal Growth Graph

When working with graphs can change or enter the patient data as follows.

Note: Select the field to be changed or entered. The system allows to input the patient data.

- LMP: the time of last menstrual period of the patient.
- BBT: the time of basal body temperature of the patient.
- GA: this field is computed using the LMP/BBT/Avg.US date on the Patient Information Window. Or show the data inputted.
- EDD: this field is computed using GA.

To change GA:

- a. Select the field.
- b. Type the correct weeks or days.

The system makes the following changes:

- GA (LMP/BBT) is now GA (GA) and shows the age entered.
- In the Patient Data section, the GA changes.
- In the Patient Data section, the EDD shows an updated date, using the GA entered.
- Fetus Position: type information about the fetus position.
- Placenta: type information about the placenta.

If there are more than one printer connected with this device, touch printer button to choose one printer. Touch ">" to configure printer's setting. Touch button "Print" to print the OB graph.

9.8.2 M Mode measurements

In M mode of Obstetrics application, it includes measurement items as follows:

- Depth
- Distance
- LVEF
- HR
- A/B Ratio

9.8.3 PW mode measurements

In "PW" mode of Obstetrics application, it includes measurement folders as follows:

- General
- Aorta
- Desc.Aorta
- Umbilical
- Placenta
- Uterus
- Follicle
- MCA

General Measurement Folder:

- Velocity
- PS
- ED
- MD
- TAMAX
- PI
- RI
- HR

Other Measurement Folders:

- Velocity
- PS
- ED
- PI
- RI
- HR

9.9 Cardiac Measurements

Based on the application of different subjects, age and weight, Cardiac measurement provides the different measurement options of each chamber and the corresponding valve in diastolic and systolic period:

- General
- LV
- MV
- Ao
- AV
- LA
- RV
- TV
- PA
- RA
- System

Overview

Cardiac measurements provide the main measurement folders: General, LV, MV, Ao, AV, LA, RV, TV, PA, RA, and System, on the B/M, CF, PW/CW/TD mode of this device.

9.9.1 General Measurement Folder

In 2D mode of Cardiac examination, the General Measurement Folder includes measurements as follows:

- Depth
- Distance
- Perimeter
- Area
- Volume
- Volume d
- Volume s
- %Stenosis
- A/B Ratio

In "M" mode of Cardiac examination, the General Measurement Folder includes measurements as follows:

- Distance
- Time
- Slope or Velocity
- A/B Ratio
- HR

In the PW mode of Cardiac examination, the General Measurement Folder includes measurements as follows:

- Velocity
- RI
- PI
- HR
- Time
- Acceleration
- A/B Ratio
- Manual Trace
- Semiauto Trace
- Auto Trace

Note: Refer to the chapter "General Measurements" for how to execute and configure the above measurements.

9.9.2 Cardiac Left Ventricular(LV) Measurement Folder

9.9.2.1 2D mode

Single distance measurement:

- LVIDd
- LVPWd
- LVIDs
- LVPWs
- LVd Major
- LVd Minor
- LVs Major
- LVs Minor
- LVOT Diam

Multiple distance measurement:

- LV Study
 - IVSd
 - LVIDd
 - LVPWd
 - IVSs

- LVIDs
- LVPWs
- LV Study (Simple)
 - LVIDd
 - LVIDs
- %FS
 - LVd
 - LVs

To complete the LV Study or LV Study (Simple) measurement, perform six or two standard distance measurements continuously.

Note: The calculation of some parameters need to use HR and BSA, where HR can be gotten from measurement HR, and BSA can be calculated through the patient's height and weight.

Area Measurement:

- 2C LVAd
- 2C LVAs
- 4C LVAd
- 4C LVAs
- S LVAd
- S LVAs
- Endo LVAd
- Endo LVAs
- EpiLVAd
- Epi LVAs
- LVOT Area

The measurement method option can be Polygon, Spline and Trace, where Trace method is the default setting.

Single Trace combined with Single Distance Measurement:

- Diastolic Period: A2C LVEDV, A4C LVEDV
- Systolic Period: A2C LVESV, A4C LVESV

When the single plane area-length method is applied, area of cross-section of the left ventricle (A), and length of the long axis of the left ventricle (L) are measured, and length of the short axis of the left ventricle (D) is calculated from these data using the following formula on the assumption that the left ventricle is a spheroid:

- A2C A-L
 - LVAd
 - LVLd
 - LVAs
 - LVLs

- A4C A-L
 - LVAd
 - LVLd
 - LVAs
 - LVLs
- Bi-plane A2C&A4C A-L
 - A2C LVAd
 - LVLd
 - A2C LVAs
 - LVLs
 - A4C LVAd
 - A4C LVAs

When the Single-plane/Enter Simpson Disc method is used, the long axes (L) of apical two-chamber or four-chamber views is divided equally into 20, and the inside diameters of the short axes (ai and bi) of 20 disks in directions perpendicular to the long axes are obtained. Left ventricular volume is calculated from the total sum of the cross-sectional areas of the 20 discs. The areas of the left ventricular cavity are obtained on the assumption that each disc is oval:

- A2C-Enter Simpson Disc Method
 - LVEDV
 - LVESV
- A4C-Enter Simpson Disc Method
 - LVEDV
 - LVESV
- Modified Simpson Disc Method
 - A2C LVEDV
 - A2C LVESV
 - A4C LVEDV
 - A4C LVESV

Auto EF

To execute this measurement item, the steps are as below:

1. Enter "Measure", select the measurement item. Select "Auto" method.
2. Touch the image, the system finishes the trace automatically.
3. Move the caliper to the green point, modify the trace line.
4. Fix the trace line.
5. Repeat step 2-4 for twice or more to complete the measurement.

The same steps can be executed for "A4C-Enter Simpson Disc Method" and "Modified Simpson Disc Method".

9.9.2.2 M mode

Single Distance Measurement:

- LVIDd
- LVPWd
- LVIDs
- LVPWs

Multiple Distance Measurements:

- LV Study
 - IVSd
 - LVIDd
 - LVPWd
 - IVSs
 - LVIDs
 - LVPWs
- LV Study (Simple)
 - LVIDd
 - LVIDs
- %FS
 - LVd
 - LVs

To complete the LV Study or LV Study (Simple) measurement, perform six or two standard distance measurements continuously.

Note: The calculation of some parameters need to use HR and BSA, where HR can be gotten from HR measurement, and BSA can be calculated through the patient's height and weight.

Single Time Interval Measurement:

- LVPEP
- LVET
- HR(R-R)

Single Velocity Measurement:

- MVcf

9.9.2.3 PW mode

Single Velocity Measurement:

- LVOT Vmax

Double Velocity Measurement:

- LVOT Max PG

- Vmax1
- Vmax2

Single Time Interval Measurement:

- LVET
- LVHR

Single Trace Measurement:

- LVOT Trace

Single Trace combined with Single Distance Measurement:

- SV (Stroke Volume)
 - SV Diam
 - VTI

9.9.3 Cardiac Mitral Valve(MV) Measurement Folder

9.9.3.1 2D mode

Single Distance Measurement:

- MV Ann Diam
- EPSS
- MR Radius (only available in the CFI mode)

9.9.3.2 M mode

Single Distance Measurement:

- EPSS

Single Slope Measurement:

- D-E Excursion
- D-E Slope
- E-F Slope

A/B Ratio(Slope):

- MVE/A Ratio
 - MV Vel A
 - MV Vel E

9.9.3.3 PW mode

Single Velocity Measurement:

- MR Vmax
- MV Vmax

Double Velocity Measurement:

- MR Max PG
 - Vmax1
 - Vmax2
- MV Max PG

- Vmax1
- Vmax2
- MV E/A Ratio
 - MV Vel A
 - MV Vel E

Single Time Interval Measurement:

- MV Acc Time
- MV Dec Time
- MVET
- MV A Dur
- MV TTP

Single Slope Measurement:

- MR Acc
- MV Acc
- MV Dec
- MV PHT
- MPA by PHT

Single Trace Measurement:

- MR Trace
- MV Trace

Multiple Time Interval Measurement:

- LV TEI Index
 - MV C-O dur
 - LVET

9.9.4 Cardiac Aortic Measurement Folder

9.9.4.1 2D mode

Single Distance Measurement:

- Ao Diam
- Ao Arch Diam
- Ao Asc Diam
- Ao Desc Diam
- Ao Isthmus
- Ao ST Junt
- Ao Sinus
- Ao Annulus

9.9.4.2 M mode

Single Distance Measurement:

- AoDiam

9.9.4.3 PW mode

Single Velocity Measurement:

- AR Vmax
- AREnd Vmax
- Coarc Pre-Dust
- Coarc Post-Dust

Double Velocity Measurement:

- AR Max PG
 - Vmax1
 - Vmax2

Single Slope Measurement:

- AR PHT

Single Trace Measurement:

- AR Trace

9.9.5 Cardiac Aortic Valve(AV) Measurement Folder

9.9.5.1 2D mode

Single Distance Measurement:

- AV Diam
- AV Cusp
- AR Radius (only available in CF mode)

Area Measurement:

- AVA
- Trans AVAd
- Trans AVAs

9.9.5.2 M mode

Single Distance Measurement:

- AV Cusp

9.9.5.3 PW mode

Single Velocity Measurement:

- AV Vmax

Double Velocity Measurement:

- AV Max PG
 - Vmax1
 - Vmax2

Single Time Interval Measurement:

- AV Acc Time
- AV Dec Time

- AVET
- AVHR

A/B Ratio (Time) Measurement:

- AV Ratio
- AV Acc Time
- AVET

Single Slope Measurement:

- AV Acc
- AV Dec
- AVA by PHT

Single Trace Measurement:

- AV Trace

9.9.6 Cardiac Left Atrium(LA) Measurement Folder

9.9.6.1 2D mode

Single Distance Measurement:

- LA Diam
- LAd Major
- LAd Minor
- LAs Major
- LAs Minor

Area Measurement:

- LAAd
- LAAs

Single Trace combined with Single Distance Measurement:

- Diastolic Period: A2C LAEDV, A4C LAEDV
- Systolic Period: A2C LAESV, A4C LAESV

9.9.6.2 M mode

Single Distance Measurement:

- LA Diam

A/B Ratio(Diam) Measurement:

- LA/Ao
 - LA Diam
 - AoDiam

9.9.7 Cardiac Right Ventricular(RV) Measurement Folder

9.9.7.1 2D mode

Single Distance Measurement:

- RVAWd

- RVIDd
- RVAWs
- RVIDs
- Basal RVD
- Mid RVD
- Base-Apex L

Area Measurement:

- RVAd
- RVAs

9.9.7.2 M mode

Single Distance Measurement:

- RVAWd
- RVIDd
- RVAWs
- RVIDs

Double Distance Measurement:

- RV Study
 - RVIDd
 - RVIDs

Single Time Interval Measurement:

- RVPEP
- RVET

9.9.7.3 PW mode

Single Velocity Measurement:

- RVOT Vmax

Double Velocity Measurement:

- RVOT Max PG
 - Vmax1
 - Vmax2

Single Time Interval Measurement:

- RVET

Single Trace Measurement:

- RVOT Trace

Single Trace combined with Single Distance Measurement:

- SV (Stroke Volume)
 - SV Diam
 - SV TAMEAN

9.9.8 Cardiac Tricuspid Valve(TV) Measurement Folder

9.9.8.1 2D mode

Single Distance Measurement:

- TV Ann Diam
- TR Radius (only available in CFI mode)

Area Measurement:

- TVA

9.9.8.2 PW mode

Single Velocity Measurement:

- TR Vmax
- TV Vmax

Double Velocity Measurement:

- TR Max PG
 - Vmax1
 - Vmax2
- TV Max PG
 - Vmax1
 - Vmax2
- TV E/A Ratio
 - MV Vel A
 - MV Vel E

Single Time Interval Measurement:

- TCO
- TV TTP
- TV A Dur

Multiple Time Interval Measurement:

- RV TEI Index
- TV C-O dur
- RVET

Single Slope Measurement:

- TR Acc
- TV PHT

Single Trace Measurement:

- TR Trace
- TV Trace

Single Trace combined with Single Distance Measurement:

- SV (Stroke Volume)
 - SV Diam
 - SV TAMEAN

9.9.9 Cardiac Pulmonary Valve(PV) Measurement Folder

9.9.9.1 2D mode

Single Distance Measurement:

- Pulmonic Diam
- PV Ann Diam

- PR Radius (only available in the CF mode)

Area Measurement:

- PVA

9.9.9.2 PW mode

Single Velocity Measurement:

- PR Vmax
- PReEnd Vmax
- PV Vmax

Double Velocity Measurement:

- PR Max PG
 - Vmax1
 - Vmax2
- PReEnd Max PG
 - Vmax1
 - Vmax2
- PV Max PG
 - Vmax1
 - Vmax2

Single Time Interval Measurement:

- PV Acc Time
- PV Dec Time
- PVET

A/B Ratio (Time) Measurement:

- PV Ratio
 - PV Acc Time
 - PVET

Single Slope Measurement:

- PR Acc
- PR PHT
- PV Acc

Single Trace Measurement:

- PAEDP
- PR Trace
- PV Trace

9.9.10 Cardiac Right Atrium(RA) Measurement Folder

9.9.10.1 2D mode

Area Measurement

- RAA_d
- RAAs

Simpson Measurement

- A4C RA Simpson

9.9.11 Cardiac System Measurement Folder

9.9.11.1 2D mode

Single Distance Measurement:

- IVC Diam
- Systemic Vein Diam
- PDA Diam
- PFO Diam
- VSD Diam
- ASD Diam
- PEd

Multiple Distance Measurement:

- %IVS
 - IVSd
 - IVSs

9.9.11.2 M mode

Single Distance Measurement:

- PEd

Multiple Distance Measurement:

- %IVS
 - IVSd
- RVd/LVd
 - RVIDd
 - LVIDd
- RVs/LVs
 - RVIDs
 - LVIDs

9.9.11.3 PW mode

Single Velocity Measurement:

- PVein Vel A
- PVein Vel S
- PVein Vel D
- Systemic Vein Vd
- Systemic Vein Vs
- VSD Vmax
- ASD Vmax

Double Velocity Measurement:

- VSD Max PG
 - Vmax1
 - Vmax2
- PVein S/D Ratio
 - PVeinVel S

- PVeinVel D

Single Time Interval Measurement:

- PVein A Dur
- IVCT
- IVRT

Single Trace Measurement:

- Systemic Vein VTI

Double Trace Measurement:

- PVA(VTI)
- Qp/Qs

10. Probes and Biopsy

10.1 Probe Overview

This device supports following types of probes

- Curved array (Convex)
- Linear array
- Phase array

10.2 Probes

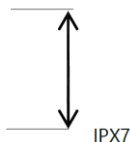
(The grade of waterproof for all convex probes, linear probes and phased array probes can refer this picture.)

3C (convex)

Center frequency : 3MHz

Frequency range in B mode : 2 ~ 5.5 MHz

Grade of waterproof : Transducer and Cable IPX7 (Except for Type C port)

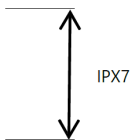


7L (linear)

Center frequency : 7.3MHz

Frequency range in B mode : 6 ~ 12MHz

Grade of waterproof : Transducer and Cable IPX7 (Except for Type C port)

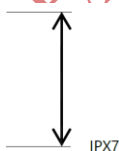


2P (Phased Array)

Center frequency : 2.8MHz

Frequency range in B mode : 2 – 3.5MHz

Grade of waterproof : Transducer and Cable IPX7 (Except for Type C port)



| Probe | Type | Intended Use | Region Applied |
|-------|--------|---|----------------|
| 3C | Convex | Abdomen, Obstetrics/Fetal, Gynecology, Urology, Pediatric | Body surface |
| 7L | Linear | Vascular, Nerve, Small Parts, Musculoskeletal, Pediatric, Vas. Access | Body surface |
| 2P | Phased | Adult Cardiac, Pediatric Cardiac, Coronary, Abdomen | Body surface |

The maximum temperature of probes' surface:

| Probe | Maximum Temperature | |
|-------|---------------------|-----------|
| | Phantom | Still air |
| 3C | 9.2 | 15.7 |

| | | |
|----|-----|------|
| 7L | 8.8 | 15.8 |
| 2P | 8.3 | 15.5 |



WARNING

The operator should always pay attention to the value of TI and MI to ensure the probe temperature does not exceed the maximum value.

Probe orientation:

Each probe has one mark in one side of the probe head. This mark indicates the start point of scanning.

Probe Labeling:

Each probe is labeled with the following information:

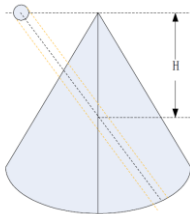
- Name of manufacture
- Model name
- Probe serial number
- Year of manufacture
- Regulatory marks

10.3 Probe connection and disconnection

Only approved probes can be connected with this device. The probe can be connected or disconnected from the probe port at any time. When the probe is connected to this device, it is automatically detected.

10.4 Biopsy

The data in the following list is the depth which is the distance between the surfaces with the cross point. The cross point is between the biopsy angle line and the center line for probes in this device. Cross point depth H can be referred the diagram as an example as shown below.



Unit: cm

| Probes for Biopsies | Fixed Angle | Multiple Angles | | |
|---------------------|-------------|-----------------|-----|-----|
| 3C | / | 4.0 | 6.0 | 8.0 |
| 7L | / | 2.0 | 4.0 | 6.0 |
| 2P | / | 4.0 | 5.5 | 8.0 |

11. System Setting

11.1 General

Enter the system settings menu, the default first entrance is "General". In the display menu, the following items can be changed.

Hospital Information

- Edit hospital name, department and address.

Time & Language

- Select time format by 12 hours or 24 hours, date format by Month-Day-Year, Year-Month-Day or Day-Month-Year.
- Select Date, Time Zone and Time. But the selected Time Zone is only effective after rebooting.
- Select which language will be used in the general. But the selected language is only effective after rebooting.

Image Setting

- Auto Optimization Mode:
 - Optimize Image: Only optimize image quality, parameters will not be adjusted.
 - Optimize parameters: Reset the value of TGC, Dynamic Range and Gain in B/HAR mode.
 - Optimize parameters and ROI: Reset the value of TGC, Dynamic Range and Gain in B/HAR mode or CF/PDI mode, and reset the size and position of ROI in CF/PDI mode.
- Image Auto Level: The level is low, medium, high.
- Auto Frequency: Change the frequency of modes automatically.
- Auto Invert when steering on flow or Doppler.

- Default state of SyncDisplay: If selecting “Enable”, when enter CF mode, it has two images on main screen, the left one is 2D image, the right one is 2D+CF image. If selecting “Disable”, when enter CF mode, it only has 2D+CF image.
- Automatically refresh tissue image when Doppler MDLine is moved: In PW mode, move MDLine, tissue image will be activated automatically for a while.
- Auto Duplex: Duplex or triplex is enabled automatically when enter PW mode if this function is enabled.
- Enable Pre Doppler Mode: “By pressing MDLine key”, “By pressing mode key”. Select “By pressing mode key”: Pressing PW key, enter pre PW mode, “Sample Volume” can be adjusted. Pressing PW key again, enter PW mode.
- Flow/Doppler Max Steer Angle: 20°, 25°, 30°, change the max angle to steer linear image.
- Full Screen: Enable it, set “Full Screen” as default.
- Scan Image Rotation: Image can be rotated 90°/180°/270° if this item is enabled.
- Display auto trace line only within heart cycle: Display green auto trace line along the valid spectrum within cycles configured by “Heart Cycle”, if this item is enabled.

Store

- Auto Cine time span: 1-1500 seconds can be selected. The default value is 5 seconds, freeze the system during scanning, enable “Cine/Single” button, the latest 5 seconds will be replayed.
- Report printing ink saving: The stored image has no background after enabled this function.

Optional Functions

- Play doppler audio for replayed doppler images: Play audio if it is enabled.
- Show tutorial control panel: Display “Tutorials” tab after enable it.
- Enable PView Advanced Features: enable this item to activate zoom in/out and move functions in PView.

UI Style

- Parameter UI Theme: There are two options: Expert, Simple. Select Expert, display all parameters.
- Select Simple, some parameters are hidden automatically.
- UI Theme: there is one option: Sky gray.

- Show Login Window: Enable it, the login window will appear when boot the system. Disable it, the system starts to scan at once when boot it.
- Show indicator on Application: Display indicator icon for applications if this item is enabled.
- Info window on Non-Main Monitor: Normal, Simple, Hide.
- Measure result position when not on main screen: Bottom right, Same as main screen.
- Measure result margin when not on main screen: 0, 1, 2, 3, 4.

Comments

- Comments fontsize: Set different fontsize for comments.
- Comments Retain After Unfreeze: Comments will not be cleared after unfreeze the system if it is enabled.
- Auto open soft keyboard when edit a comment.
- Use "Common" comments as default: "Common" tab is selected when enter "Comments" if it is enabled.

Patient/Exam

- Default New Patient UI: Local Data, Worklist.
- Patient ID prefix: Add prefix for patient ID.
- Patient Weight and Height Units: Metric Units, Imperial Units.
- Patient name format: First (Middle) Family, Family (Middle) First.
- Accession number Format: None, PatientID and IncrementNumber, ExamDate and IncrementNumber, Patient Name and IncrementNumber.
- Show patient birthday on image: Disabled, Enabled, Age (display age not birthday).

Body Pattern

- Body Pattern size: Adjust the size of body pattern displayed on the image.
- Auto flip body pattern when change display from Single to Dual: The selected body pattern will be flipped automatically when switch display format from single to dual if this function is enabled.
- Default location in visual for body pattern: Top Left, Top Right, Bottom Left Bottom Right.
- BodyPatter Retain After Unfreeze: Disable this function, the body pattern will be removed from the image after unfreeze the system.
- Set "Common" as default: "Common" tab is selected when enter "Comments" if it is enabled.

Biopsy

- Biopsy line type: Guide line, Parallel Region, Guideline and Tolerance Line.
- If select "Parallel Region", user can select Biopsy Parallel Line Distance: 0.4, 0.6, 1, 1.2, 1.6, 2.

Input Setting

- Caps Lock as default: Set "Caps" as default for Alphanumeric keyboard.
- Hide softkey board while using external keyboard: When plug in one external keyboard, the soft keyboard will not come out if it is enabled.
- Window open after freeze: Enter Measure when freeze the system, if select "Measure". Enter Comments when freeze the system, if select "Comments". Enter Body Pattern when freeze the system, if select "Body Pattern". Just freeze the system if select "Do nothing".

Power Saving

- Auto Freeze after a period of idle time (minutes): Never, 2,5, 10, 15, 30, 45, 60. 5 is the factory setting, if the system run 5 minutes with no operation, it will be frozen.
- Turn off the display while freezing automatically: Turn off the screen while the system freezing automatically. Press any key or touch the touch panel to activate the screen again.
- Touch "User manual", open the User manual page. Touch "<", closed user manual.

After changing settings, select "V" to save the information and exit from system setting menu. Select "X" to exit from the system setting menu without saving any information.

11.2 Measurement

Please refer to Chapter "Measurement system setting" of Measurement and calculation

11.3 Extended key

Printing and Save Keys in Probe:

There are three keys on the device, they can be configured in Sys Setting.



WARNING

The operator must make sure that USB memory stick is virus-free before connecting it with this device. Run a virus scan for USB memory stick in your computer before using.

The following functions can be configured into those three keys, 2 external foot switches.

- Store

Select "Details" to select different destinations and file formats.

- Destination:
 - HDD
 - USB
 - File Server (need to connect to one file server first)
 - DICOM Storage Server (need to connect to one DICOM storage server first)
 - FTP Server (need to connect to one FTP server first)
 - vCloud server (need to connect to one vCloud server first)
- File Format:
 - VRD
 - DICOM
 - AVI or Image (Image Compress method: PNG, JPEG, BMP, TIFF)
- Time span: for storing live scan image
 - VRD: 1-1500 seconds
 - DICOM/AVI: 1-30 seconds
- Store Mode:
 - One key Store
 - Record Mode
- Freeze/Unfreeze
Save Screen Shot to USB: Press the corresponding key to save the snapshots of touch panel.
- Perform Function
 - Measure
 - BodyPattern
 - Comment
 - DecreaseDepth
 - IncreaseDepth
 - DecreaseGain
 - IncreaseGain
 - HAR
 - CF
 - PDI
 - M
 - PW
 - Enter
 - Auto
 - Left

➤ Right

Enter related function after press the related key.

- Do nothing

Note:

1. If store file format is VRD or DICOM, there is an option "Store single frame image", after it is enabled one single frame image is stored even when the system is in live scan mode.
2. If "Include patient info" and "Include hospital info" is enabled, preview the stored image in Report, there are patient ID, name and hospital name on the image.
3. If store destination is USB, DICOM Storage Server, File Server or FTP Server, there is an option "Backup stored file in Local Machine", after it is enabled, the image will be stored to the server and HDD.
4. If store destination is DICOM Storage Server or FTP Server, there is an option "Auto image data transfer after end exam". If it is enabled, the image will be stored to the server after the exam is ended. If it is disabled, the image will be stored to the server immediately.

Factory default configuration as below:

- "Store" key: Store VRD to HDD
- "Button 1" key: Do nothing.
- "Button 1" key: Do nothing.
- "Button 1": Do nothing.

11.4 Network

Please ONLY use the hospital's LAN.

Note:

- Connection of the ultrasound diagnostic apparatus to an IT-NETWORK that includes other equipment could result in previously unidentified RISKS to PATIENTS, OPERATORS or third parties;
- The RESPONSIBLE ORGANIZATION should identify, analyze, evaluate and control these RISKS;
- Subsequent changes to the IT-NETWORK could introduce new RISKS and require additional analysis;
- Changes to the IT-NETWORK include:
 - changes in the IT-network configuration;
 - connection of additional items to the IT-NETWORK
 - disconnecting items from the IT-NETWORK;
 - update of equipment connected to the IT-NETWORK; and
 - upgrade of equipment connected to the IT-NETWORK.

11.4.1 General

This configuration category enables the operator to set the network for the system and connected remote archive.

If one network cable is plugged in, the operator can do the following settings to connect the network:

- If enable "Auto config IP address", the system will connect to the network automatically.
- If disable "Auto config IP address", the operator needs to input IPv4, Subnet mask and Default gateway.

If one wireless network adaptor is plugged in, the operator can do the following settings to connect the network:

- Reboot the system after plug in the adaptor,
- Select one network, input the password, then touch "Enter";
- Or select "Other", input the network name and password, then touch "Enter". Touch "Refresh" to update wireless network list.
- Touch "Unsave" to disconnect the current connected network.

11.4.2 File Server

If the operator wants to connect one server:

- Input the server address in "Server Path", and touch "Confirm".
- If the server needs authentication, enable "User Authentication" then input username and password.
- After all settings are ready, select the "✓" key to save all setting in the system.

11.4.3 Email Setting

- Email Account: Input the email account here for sending emails.
- Email Password: Email account's password.
- SMTP Server: Input SMTP server here.
- SMTP Port: Input SMTP port here.
- Secure Mode: There are 2 secure modes, "Normal" and "SSL".
- Email Subject and Email Body: There is default template of email subject and email body, the operator can edit them.
- Addressee: Input one addressee here and select "Test" to test the email account setting.

11.4.4 FTP

- FTP server address: Input FTP server address.
- FTP server port: Input FTP server port.
- FPT sub folder: Input the store path on the server.
- FTP account: Input FTP account.

- FTP password: Input FTP password.
- Enable FTP storage: Enable it to connect FTP server.

During uploading, there is an icon showing the number of the uploading images. If the file upload to server failed, there will be an error icon on the right bottom corner of the main screen. Click the icon, popup the file list of fail uploaded. Select “Retry” to upload again, or select “Delete” to delete the file.

Images of all formats can be uploaded to FTP server, but only DICOM images can be downloaded and viewed.

11.4.5 vCloud Server

Touch “Enable” to activate this function.

The default server is “VINNO vCloud Server”, touch “Test” to try to connect to the server.

The following information is needed to input if touch “Add” to connect another server:

- Server name
- Server address
- Server port
- Account
- Password

Please contact PT. SINKO PRIMA ALLOY service to create a new server.

Remote Maintenance: After enable this function, user can get log, push patch, do remote control through FLYINGSONO.

11.5 DICOM

11.5.1 General

- **DICOM file format:**
 - Lossless bitmap
 - Lossless
 - Compressed .jpeg
 - Lossy compressed .jpeg
- **DICOM Compress mode**
Full compatibility
Suitable for PT. Sinko Prima Alloy: Store one DICOM video, play it on PC with DICOM player, it is not a video but one frame image.
Suitable for third party: Store one DICOM video, play it on PRO SCANNER machine, it is not a video but one frame image.
- **DICOM default encoding:** Different encoding methods.
- **Patient Name Format:** Family Name^First Name, First Name^Family Name, Family Name^FirstName^Middle Name, First Name^FamilyName^Middle Name.
- **Frame Rate:** Default, 15,12

- **Local setting:**
 - Local AET : input service class user's application entity title
 - Local Address : input service class user's address
 - Local port : input service class user's port

11.5.2 Storage

- Storage SCP AET : input service class provider's application entity title
- Storage SCP address : input service class provider's IP address
- Storage SCP port : input service class provider's port
- Enable storage : enable it, save DICOM image to PACS server. Please select "Save DICOM to HDD and DICOM server" in "Extended key".

Only DICOM image can be uploaded to DICOM Storage Server. During uploading, there is an icon showing the number of the uploading images.

If the file upload to server failed, there will be an error icon on the right bottom corner of the main screen. Click the icon, popup the file list of fail uploaded. Select "Retry" to upload again, or select "Delete" to delete the file.

11.5.3 Worklist

- Worklist SCP AET : input service class provider's application entity title
- Worklist SCP address : input service class provider's IP address
- Worklist SCP port : input service class provider's port
- Enable Worklist : enable it to get patient list from server.

Worklist Special Config:

- Specify Local AET : Only list the patient(s) whose AET is the same with the local AET set in General if it is enabled.
- Force Date Format : Only start date can be selected when filter the patients if it is enabled, the end data is the current data.
- Auto Load Worklist : Get the patient list from worklist server automatically if it is enabled. Convert patient name to Double-byte for querying. End query when end of sequence.
- Patient Name Format : Family name at the first, or first name at the first.

11.5.4 Print

- Print SCP AET : input service class provider's application entity title
- Print SCP Address : input service class provider's IP address
- Print SCP port : input service class provider's port
- Enable print : Enable it to connect the DICOM printer.

11.6 Service Tool

This menu includes auto diagnostic functions for each electrical part and catches software log files in order for engineers to identify the root cause.

11.6.1 Demo Mode

Enable this function, loop playback the images in the clipboard.

11.6.2 Display Backlight Config

The display backlight of Main Screen can be adjusted and reset.

11.6.3 Power Information

Display battery information: capacity percent, charging state and other.

11.6.4 Software Log File Download

There is one "Report" button to send this issue to service engineer.

- Report Current Issue : input some words to describe the issue.
- Report : Copy the description words to the log
- Download log file : Download all log files to one connected USB device.

11.6.5 Export/ Import UserDefine Configuration

- Export to USB: Export all user defined data to one USB device, include data of "Application&Parameters", "Measurements", "Comments", "System Setting", "OB Tables", "Stress Echo", "Body Patterns", "Report Comments", "Report templates", and "Strain Rate". Select "Export" to start.
- Import from USB
 - Select "Import", come out one dialog for the operator to select which item is needed to import.
 - If there is no user defined data, "Empty User Define config" will be displayed.
 - If there is user defined preset, please select probe and application which is needed to be imported.
 - If select "Keep them" in "How to deal with the other user defined presets on this machine?", all user defined presets will be kept. If select "Remove them". All user defined presets will be cleared before import user defined presets from USB disk.
- Delete User Defined Preset: After select "Delete", the system need to restart. Then all user defined preset will be cleared. Delete All User Defined Configuration: After select "Delete", the system needs to restart. Then all user defined configurations are cleared, all settings are reset as factory default.

11.6.6 System Upgrade

There is one "Check" button to check the system upgrade.

- Plug in USB memory stick
- Select "Check" button

The system will check the available new version software from the USB memory stick. If the USB memory stick has valid upgrade, select "OK", the system start upgrade.

11.7 Features

- Installed Features: List all features can be used at the current moment, including standard features and optional features that already got license.
- Available Features: List all features those are optional but no license.

11.8 User Management

This section defines the operator's ID, the operator's authority and login procedure setting. Start the system with "Show Login window" enabled, the operator can select "User Management" in "System Settings".

Authority levels:

1. Administrator: can add, modify and delete a user.
2. No authority (selecting "Cancel" to login): cannot add, modify or delete a user.

The following steps show how to manage users.

Add New User:

- Input "User Name", "Password".
 - Select "Admin" (administration) or "User" authority.
 - Select "Enter" button to confirm adding action
- The factory default Administrator account is as below:
- | | |
|----------|---------|
| Name | : admin |
| Password | : admin |

Modify User:

- Select the edit button of one user.
- Edit its name and password, then select "Enter".

Remove operator:

- Select the user to be removed in user list.
- Press "X" button to delete this user.

11.9 About

This section displays "Software Version", "Hardware Version", "DongleId", "License", "CopyRight".

12. Operator Maintenance and Technical Data

12.1 System maintenance

As there are no components with short working lives, periodic maintenance inspection is not mandatory. However, some customer quality assurance programs may require the additional inspections at periods of frequency different from those listed in this manual.

The manufacture will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of the equipment that are designated by the manufacture as repairable by service personnel.



CAUTION

The operator must ensure that safety inspections are performed at least every 12 months according to the requirements of the patient safety standard IEC 60601-1. Only trained persons are allowed to perform the safety inspections mentioned above. To ensure maintaining good operating

conditions of this device, we recommend the customer internal maintenance plan includes the following procedures.

12.1.1 Inspecting this device



CAUTION

If any defect is observed, DO NOT operate this device and inform a qualified service person. Inspect the following parts on a monthly basis:

- Connectors on cables, for any mechanical defects
- Entire length of electrical and power cables, for cuts or abrasions
- Equipment, for loose or missing hardware
- Control panel and touch panel defects
- Caster brakes



WARNING

To avoid electric shock hazard, DO NOT remove panels or covers from this device.

12.1.2 Virus protection

To minimize virus vulnerability this device is configured with a minimal set of open ports and all network services not active used. This significantly reduces the risk of a virus attack. PT. SINKO PRIMA ALLOY Company is continuously assessing the need for additional actions to reduce vulnerability of equipment; this includes vulnerability scanning of our products and evaluation of new security patches for the third-party technology used.



CAUTION

This device should only be used with an internal Local Area Network (LAN).

12.1.3 Cleaning this device

Frequent and diligent cleaning of this device will reduce the risk of spreading infection from person to person, and also help maintain a clean working environment.

When performing cleaning procedures, to prevent the risk of system damage, always observe following precautions:

- Use only recommended cleaning materials and solutions
- Do not spray any liquid directly onto this device.
- Do not allow any liquid to drip or seep into this device.
- Prior to cleaning, turn OFF power of this device

System cabinet cleaning:

- On a weekly basis, moisten a soft, non-abrasive folded cloth or sponge with a mild, general purpose, non-abrasive soap and water solution. DO NOT use any solution containing abrasive powder or strong chemicals such as acid or alkaline. Squeeze excess liquid from the cloth/sponge, and then wipe down the top, front, back and both sides of this device.
- Rinse the cloth/sponge with clean running water and wipe this device surfaces again.
- Use a dry, soft, line-free cloth to dry this device surfaces.

- Wait for this device surfaces to dry completely before turn on the system.

Note: If disinfection is required, wipe with a soft, dust-free cloth and a small quantity of isopropyl alcohol.

Monitor cleaning:

On a weekly basis, gently wipe the monitor display with a dry, soft, lint-free non-abrasive folded cloth. Wipe or dust the stain gently with a soft, dry cloth. If the stain remains, moisten a soft, lint-free cloth with water or a 50/50 mixture of isopropyl alcohol and water. Wring the cloth to remove as much liquid as possible then wipe the monitor again.

12.1.4 Service life

| Device/accessories | Intended service life |
|--------------------|---|
| PRO SCANNER | This system is expected to be used for at least 5 years from the date of production under regular maintenance and the production date is showed on the product label. |

12.2 Technical Data

12.2.1 General

Model : PRO SCANNER

Serial number : marked in identification plate on the rear side of this device

Identification plate example: PRO SCANNER CONVEX ARRAY



Electro-magnetic influence: In the working frequency range of the ultrasound system from 1 to 18MHz can be visible in the range from 200 to 500mV/m influence depending on the probe connected.

Safety classification:

- Type: Class II and internal power
- Type BF applied part: Ultrasound probe
- No defibrillation-proof applied part
- Waterproof level: IPX0, except transducer lens and probe housing is IPX7
- NOT category AP equipment or category APG equipment
- Sterilization shall be taken by other methods validated and described by the MANUFACTURER.
- Ordinary Equipment/Continuous Operation
- Not intended for use in an OXYGEN RICH ENVIRONMENT

Ambient temperature: 10°C to 35°C or 50°F to 95°F of operational temperature.

Relative Humidity : 30% to 75% in operation.

Stock & transportation temperature : -5°C to 50°C or 23°F to 122°F.

Stock & transportation humidity : less than 80% RH, no condensation.

Barometric Pressure: 700 to 1060 hPa

Dimension

Linear array probe 7L series : 183 by 59.2 by 27 mm (L x W x H)

Phased array probe 2P series : 186.5 by 59.2 by 27 mm (L x W x H)

Convex array probe 3C series : 186.9 by 59.2 by 27 mm (L x W x H)

Weight: 340g (probe only)

12.2.2 Power Supply

Power requirement : 100V-240VAC 50Hz-60Hz

Power consumption : 60VA.

12.2.3 Operator Panel

Control panel: 8"projected capacitive touch panel in high resolution and color. And it is the operator-defined and configurable layout UI.

12.2.4 Console Design

1 active probe ports

12.2.5 Transmitter

Frequency range: Broadband system 1 to 18MHz, automated adaptation to the probe used.

Control of acoustic output: 10% -100%

Focusing: selectable transmit focal width and focal depth

12.2.6 Receiver

Frequency range: Broadband system 1 to 20MHz, automated adaptation to the probe used.

Focusing: Digital dynamic focusing system, accuracy of focus: +/- 5ns. Sample-rate: 50MHz.

12.2.7 Scan Converter

Image resolution: 1920 x 1080

Image Lines: max 1024

Scan angle: max 90 degree

12.2.8 Cine Loop Memory

Call back sequence: manually frame by frame. Call back automatically from 20% to 400% of real time rate with selectable start and end point.

12.2.9 Basic Measurement Accuracy

The table below lists the basic measurement accuracy of this device, in order to guide the operator to use this instrument for clinical diagnosis when the number of changes or measurement error may arise. The error may be due to the limitations of the instrument itself or inappropriate operation of the operator. If an operator regulates the operation according to the operational guidelines, can make the potential measurement error reduced to a minimum.

| Measurement | | Unit | Accuracy | Conditions |
|------------------|--|-------------------|--------------------------|-----------------|
| Distance | Lateral | mm | ±5% | B B Harmonic |
| | Axial | mm | ±5% | |
| | Depth | mm | ±5% | |
| Perimeter | L&W Ellipse Polygon Spline Trace | mm | ±10% | |
| Area | L&W Ellipse Polygon Spline Trace | mm ² | ±10% | |
| Volume | L&W&H | mm ³ | ±30% | |
| Angle | | deg | ±5% | |
| Time | | s | ±5% | M, PW |
| Slope | Velocity | mm/s | ±10% | M |
| | Acceleration | mm/s ² | ±10% | PW |
| SV Depth | | mm | ±2mm | PW |
| Velocity | | cm/s | 0 – 130 cm/s : ±2% | PW |
| | | | 50% (only for reference) | CF |
| Angle correction | | cm/s | 0 – 60 deg: ±10% | PW |
| | | | 60 – 80 deg: ±12% | |

13. Probe Maintenance



CAUTION

Improper handling can lead to early probe failure and electric shock hazards. Only follow the specific cleaning and disinfection procedures provided in this chapter and the germicide manufacturer's instructions.

Improper cleaning and disinfection procedures will result in probe failure which will void probe warranty.

13.1 Inspecting the probe

After each use, needs to inspect the probe, clean the probe and disinfect the probe if required. Inspect the transducer cable, case, and lens before each use.



If any damages are found, DO NOT use the probe until it has been inspected and released for further use by PT. SINKO PRIMA ALLOY qualified person.

After each use, inspect the lens, the probe housing and the cable as shown below figure. Check whether there is damage area that might allow the liquid into the probe.



Before each use, inspect the lens, the probe housing and the cable. Check whether there is damaged area that might allow liquid into the probe. When connected to this device, needs to test the functionality of the probe.

Note:

Only qualified ultrasound gel is approved for use.

13.2 Special handling instructions

Using protective sheaths:



Protective barrier may be required to minimize disease transmission.

Use of legally marketed, sterile probe sheath is strongly recommended for intra operative procedures.

Instructions

Each probe sheath kit consists of a flexible and elastic sheath which can cover the probe and cable.



DO NOT use an expired sheath. Before using probe sheaths, verify whether the term of validity has expired. Also read sheath document carefully to avoid allergic reaction in sensitive individuals.

13.3 Probe handling and infection control

This information is intended to increase user awareness of the risks of disease transmission associated with using this equipment and provide guidance in making decisions directly affecting the safety of the patient as well as the equipment user.

Diagnostic ultrasound systems utilize ultrasound energy that must be coupled to the patient by direct physical contact. Depending on the type of examination, this contact occurs with a variety of

tissues ranging from intact skin in a routine exam to re-circulating blood in a surgical procedure. The level of risk of infection varies greatly with the type of contact.

One of the most effective ways to prevent transmission between patients is with single use or disposable devices. However, ultrasound transducers are complex and expensive devices that must be reused between patients. It is very important, therefore, to minimize the risk of disease.



CAUTION

Risk of Infection: ALWAYS clean and disinfect the probe between patients to the level appropriate for the type of examination and use cleared probe sheaths where appropriate.



CAUTION

Adequate cleaning and disinfection is necessary to prevent disease transmission. It is the responsibility of the equipment user to verify and maintain the effectiveness of the infection control procedures in use. Always use sterile, legally marketed probe sheaths for intra operative procedures.

For neurological intra-operative procedures, use of a legally marketed, sterile, pyrogen free probe sheath is REQUIRED. robes for neuro surgical use must not be sterilized with liquid chemical sterilants because of the possibility of neuro toxic residues remaining on the probe.

13.4 Probe Safety



WARNING

Ultrasound probes are highly sensitive medical devices that can easily be damaged by improper handling. DO NOT use a damaged or defective probe. Failure to follow these precautions can result in serious injury and equipment damage.

13.5 Cleaning and Disinfecting Probes



CAUTION

Refer to the user documentation enclosed with these probes.



CAUTION

You MUST disconnect the probe from the USG PRO SCANNER prior to cleaning/disinfecting the probe. Failure to do so could damage the system.

13.5.1 Cleaning Probes

Cleaning procedure

1. Disconnect the probe from the unit.
2. Remove the coupling gel by wiping the probe lens with a soft cloth.
3. Wipe the probe and cable with a soft cloth moisten in a warm soap and water solution (<80oF/27oC).

4. Wipe the probe and cable with a soft cloth moisten in clean water (<80oF/27oC) until all soap is removed.
5. Wipe dry with a soft towel.



CAUTION

To minimize the risk of infection from blood-borne pathogens, you must handle the probe and all disposables which have contacted blood, other potentially infectious materials, mucous membranes, and non-intact skin in accordance with infection control procedures. You must wear protective gloves when handling potentially infectious material. Use a face shield and gown if there is a risk of splashing or splatter.

13.5.2 Disinfecting probes

Disinfecting probes

Although representing a necessary step in protecting patients and employees from disease transmission, liquid chemical germicides must also be selected to minimize potential damage to the transducer. It is important to use germicides of probe recommended by PT. SINKO PRIMA ALLOY.

Below is the list of germicides for each probe:

- Alkazyme
- Klenzyne
- Steranios 2%
- Cidex OPA

Disinfection

After cleaning, the probe and cable may be wiped with a tissue sprayed with a recommended disinfectant. When decontaminating an infected probe, use additional precautions such as gloves and gown.

Returning/shipping probes and repair parts

When return a probe or part for service, needs to clean and disinfect the probe or part prior to packing and shipping this device. Ensure that the follow probe cleaning and disinfection instruction. This ensures that the employees in the transportation industry as well as the people who receive the package are protected from any risk.

13.6 Coupling Gels



CAUTION

Do not use gels (lubricants) that are not recommended. They may damage the probe and void the warranty.

In order to assure optimal transmission of energy between the patient and probe, a conductive gel or couplant must be applied liberally to the patient where scanning will be performed.

Note:

We do not recommend that the operator use colored ultrasound gel. Long-term use may cause discoloration of the probe housing, although the discoloration does not affect the performance and functionality of the probe.

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